Exploring the Theory-Practice Gap in Public Health interventions:

a critical assessment of the potential for Normalisation Process Theory to aid knowledge transfer into practice, using the evaluation of a complex smoking cessation in pregnancy initiative

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Abstract

This thesis arises from the observation that complex interventions in public health, even when devised from high-quality, trial-based evidence, often fail to achieve expected outcomes and impact in practice. Data from a process evaluation of the implementation of a stop smoking in pregnancy initiative were used to explore this theory-practice gap, using Normalisation Process Theory (NPT). The aim of the thesis is to examine the utility of NPT in understanding both this gap and the challenges to implementing evidence-based, complex, public health interventions.

North East England is an area with high levels of smoking at time of delivery, (around 20%) when compared to national figures (average around 13%) at commencement of the study in 2012. Good evidence-based advice exists to address this issue (NICE, 2010) but local maternity staff had struggled to implement it. This led to the implementation of the example intervention, babyClear©, a package of measures which included standardising: carbon monoxide monitoring, opt-out referral to stop smoking services, enhanced follow-up and a risk perception tool.

NPT showed promise as an analytical tool, since it focuses on eliciting the implementation process of an intervention, and its feasibility and sustainability in context. A logic model was used to hypothesise the intervention process, which was subsequently compared with the findings from a thematic analysis, followed by analysis of the intervention and implementation using NPT.

NPT proved sufficiently flexible to use summatively in the evaluation cycle. Elements of the theory-practice gap, largely overlooked in trials evidence, were elucidated through clarifying other active ingredients and mechanisms of delivery. Environmental contexts were not completely captured by NPT. Data on sustainability and transferability were limited; however, it was found that NPT can identify factors that are likely to influence them. There were some challenges associated with using NPT, and core concepts required redefining to translate and adapt them for use in this study.

In conclusion, NICE Public Health Guidance (2010) is principally based on evidence from trials and would benefit from being combined with knowledge derived from research based on social theories, such as NPT. Routinely incorporating NPT, or similar, should be considered when implementing trial-based interventions into complex, public health systems.

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This thesis has taken 5 years to complete and many changes have occurred in the home and work lives of myself, my family and my supervisory team in that time.

I would just like to express my huge gratitude to my supervisors,

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Professor Janet Shucksmith and

Professor Anna van Wersch

and also to my husband, Jamie Jones

… for persevering alongside me and continuing to support and believe in me through all the ups and downs.

Just to keep this doctoral thesis in perspective …

"… what we may think of as final products of research, are just a momentary pause in an endless flow" (Crang, 2003, p135).

And the challenges working against completion …

"One must choose one's conversation partners, referring to others only where necessary for the argument. If one were even to try to 'catch up' with everything that had been written at the time of going to press, one would put off forever going to press" (Wright, 2001, pxvi).

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Glossary

AI providers	Active Intervention providers
ASH	Action on Smoking and Health
CASAA	Consumer Advocates for Smokefree Alternatives Association
CCG	Clinical Commissioning Group
CO	Carbon Monoxide
CQUIN	Commissioning for Quality and Innovation
COREQ	COnsolidated criteria for REporting Qualitative research
CRUK	Cancer Research UK
DH	Department of Health
DHSC	Department for Health and Social Care
eNPT	extended NPT
GP	General Practitioner
HCP	Health Care Professional
HoM	Head of Midwifery
IPiP	Improving Performance in Practice
JBI	Joanna Briggs Institute
KT	Knowledge Translation
LA	Local Authority
MCA	Maternity Care Assistant
MRC	Medical Research Council
NE	North East
NHS	National Health Service
NHSE	NHS England
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPM	Normalisation Process Model
NPT	Normalisation Process Theory
NRT	Nicotine Replacement Therapy
PbR	Payment by Results
PCT	Primary Care Trust
PH	Public Health
PHE	Public Health England
ppm	parts per million
PT	Participant
RQ	Research Question

RCT	Randomised Controlled Trial
RPT	Risk Perception Tool
RCGP	Royal College of General Practitioners
RCM	Royal College of Midwives
RCP	Royal College of Physicians
SATOD	Smoking At Time Of Delivery
SC	Smoking Cessation
SDM	Service Delivery Model
SHA	Strategic Health Authority
SiP	Smoking in Pregnancy
SPHR	School for Public Health Research
SS	Stop Smoking
SSPS	Stop Smoking in Pregnancy Services
SSS	Stop Smoking Service (local authority)
TAG	Tobacco Advisory Group
ToC	Theory of Change
WP	Work Package

PART 1

Part 1 comprises the first three chapters (Introduction, Research Environment and Normalisation Process Theory (NPT)). It paints the background to this doctoral exploration and establishes the intention of the research questions asked in the thesis. It provides a general introduction to the main issues, gives background information on the intervention example - 'babyClear©', offers an overview of the current research environment in public health, and finally outlines an introduction to NPT.

According to Rose (1982) the research process has five distinct components: theory, theoretical propositions, operationalisation, field-work and results. This chapter introduces the first two in this list. It begins by introducing the research environment when evaluating complex interventions and the theory of interest, that is, Normalisation Process Theory. Operationalisation, fieldwork and results are covered in Chapters 4 – 8. This introductory chapter briefly explains where the idea for the thesis came from and the nub of the questions it seeks to answer i.e. the utility of NPT in illumining the theory-practice gap. Some initial, background literature is used to provide a platform to underpin the study. The key issue, over-reliance on a positivist ontology and epistemology, when researching complex, public health interventions, is introduced, as is the evaluation guidance and theory foundational to the thesis. The research aim, questions and plan of the thesis are also stated. Then the source of the data for the secondary analysis, a process evaluation of the implementation of a stop smoking (SS) in pregnancy initiative, is introduced.

Chapter 1 INTRODUCTION

This thesis investigates a challenging area in contemporary healthcare practice – namely, why and how some evidence-based, complex interventions are assimilated into practice while others are neither sustained nor impactful. This theory-practice gap (sometimes known as the theory-implementation-practice gap or knowledge-attitudes-practice gap) has been the subject of extensive research over the last decade; arguably it results from over-reliance on a positivist ontology and epistemology using trial methodologies to study complex, public health interventions (Zapka *et al.*, 2004; Straus, 2009; Fletcher *et al.*, 2016; Walton, 2016). In trial designs, complexity is largely overlooked and the 'active ingredients' and 'mechanisms of delivery and impact' are not always made explicit (Moore *et al.*, 2014). This acts as a barrier to innovations being embedded and becoming a 'normalised' part of routine, healthcare practice (May, 2006).

1.1 Origin of the thesis

The research questions originated in a process evaluation undertaken as part of a mixed method evaluation study. This mixed method evaluation focused on a public health intervention that consisted of a package of measures (hereafter called babyClear©) to reduce rates of Smoking in Pregnancy (SiP). The intervention was developed pragmatically by midwives and for midwives, to assist them in supporting pregnant women to quit smoking (Fendall *et al.*, 2012). SiP is known to cause an array of negative health effects for mother and baby as reported by the Royal College of Physicians (RCP) and Tobacco Advisory Group (TAG) (2010); therefore, it is important that pregnant women are offered advice and support to quit. National Institute for Health and Care Excellence (NICE) *Public Health (PH) Guidance 26: Smoking – stopping in pregnancy and after childbirth* (2010) (hereafter known as NICE PH Guidance (2010)) recommends this advice and support as part of routine maternity care. However, (Beenstock *et al.*, 2012) found that across the North East (NE) of England this guidance had not been fully implemented.

In response to these findings, and the high rates of Smoking at Time of Delivery (SATOD) in the region, babyClear© was introduced. It was rolled out across the NE from 2012 – 2015. This involved eight National Health Service (NHS) Foundation Trusts and all stop smoking in pregnancy services (SSPS) in the region. This was an intervention that was complex, being implemented within a complex system, and fits the definition for a complex intervention: "an intervention comprising **multiple components** which interact to produce change. Complexity may also relate to the **difficulty of behaviours targeted** by interventions, the

number of organisational levels targeted, or **the range of outcomes**" (Moore *et al.*, 2014, p8).

BabyClear© has a public health remit, that is, it is an intervention 'focused upon primary or secondary prevention of disease, or positive health promotion, rather than treatment of illness' (Moore *et al.*, 2014, p8). The initial evaluation of the implementation of babyClear© commenced in 2012 and was a collaborative venture between Newcastle and Teesside Universities under the banner of Fuse (The National Institute for Health Research (NIHR) funded Centre for Translational Research in Public Health). The Newcastle team led the effectiveness and cost-effectiveness aspects of the evaluation (Bell *et al.*, 2018) (Appendix 11.1.1). The Teesside team (Professor Shucksmith, Professor Hamilton and myself, Susan Jones) focused on the process evaluation and aimed to assess various aspects of the implementation including: a) fidelity, b) impact on services, c) acceptability to staff, d) likelihood of sustainability and e) perceptions of acceptability amongst pregnant women.

This collaborative, primary study left me with further questions about how a supposedly standardised intervention was implemented in different ways and, in some cases, stalled completely, despite initial high hopes for its effectiveness across the region by the funders and researchers. This was not the only case of this type; the Family Nurse Partnership and Sure Start models for example – both transferred from America – failed to live up to the promise they appeared to offer (Welshman, 2010; Robling *et al.*, 2016; Sanders *et al.*, 2019). In my thesis, I explore NPT as a potential theory for investigating these questions of differential implementation.

This thesis is based on a secondary analysis of the qualitative data collected from staff during the primary study. The aim of the primary data analysis was to answer questions of acceptability and fidelity of the intervention for two study groups: pregnant women and staff (maternity and stop smoking services). Although the primary study was in collaboration with Newcastle University, all the data collection and the majority of the initial data analysis, even at this stage, was carried out by me (supported by Professor Shucksmith and Professor Hamilton). This is reflected in Jones *et al*. (2019), where I wrote the first draft and am first author on the paper arising from the process evaluation.

The secondary analysis of this data was specific to the thesis and not part of the work for the initial evaluation. The aim of the analysis for the thesis was completely different from the primary study. It was focusing on the use of NPT, not the attributes of the intervention, its application in practice or even the journey of normalisation itself. The focus was the

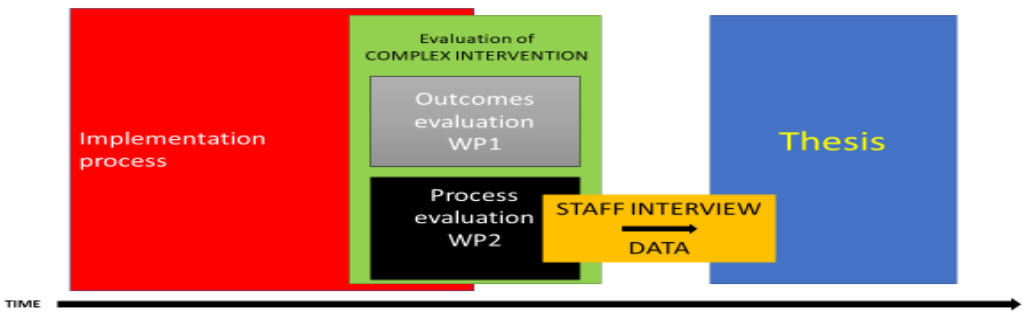
application of theory and its usefulness for purpose. Further, the lack of programme logic and the importance of context, that the primary analysis identified, was exclusively explored and written up for the thesis. Therefore, data collected from patient interviews are excluded as their principal focus is patient perspectives on acceptability of the intervention; while the focus of this thesis is the utility of NPT. The intervention is an example only; a scaffold for examining NPT. I am not examining intervention effectiveness or acceptability to pregnant women. Instead, I am concentrating on normalisation within an organisation from a staff perspective; which is consistent with the stated purpose of NPT i.e. a means to understand the organisational process of implementation (May and Finch, 2009).

1.2 Relationship of the thesis to the evaluation

The intervention, babyClear©, is typical of public health interventions in terms of its complexity, setting and the broad population group to which it was applied (Moore *et al.*, 2014; Sitton-Kent, 2016). The evaluation study design spanned two work packages (WPs), WP1 and WP2, (see Figure 1-1), of which only WP2, the process evaluation, is of interest here.

A process evaluation is a non-experimental method, sometimes used alone or, arguably for a stronger design in certain circumstances, in combination with an experimental method (Greenhalgh *et al.*, 2009; Moore *et al.*, 2014). “Process evaluations, which explore the way in which the intervention under study is implemented, can provide valuable insight into why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised. A process evaluation nested inside a trial can be used to assess fidelity and quality of implementation, clarify causal mechanisms, and identify contextual factors associated with variation in outcomes” (Craig *et al.*, 2013, p591).

Figure 1-1: Relationship of the thesis to the mixed method study design



WP1 = work package 1; WP2 = work package 2.

The process evaluation (WP2) comprised of data collection and analysis of the implementation process from the perspective of various stakeholders. However, in the thesis my focus was the theory (NPT), not the study populations. Therefore, I took the analysis in a different direction to explore the utility of NPT in more detail. I wanted to identify its contribution to understanding the extent to which a specific, evidence-based health care intervention, babyClear©, was assimilated into routine practice, i.e. normalised, and sustained. My aim was to see what NPT had to offer in narrowing the theory-practice gap (May and Finch, 2009; Straus, 2009; McCleary *et al.*, 2013; Walton, 2016). Terms used to describe discrete bodies of work can be found in Table 1-1.

Table 1-1: Descriptive terms used in the thesis for discrete bodies of work

Term	**Description**
Intervention	babyClear© - the example - as developed and delivered by practitioners
Evaluation	[WP1 – outcomes; not the focus of this thesis] WP2 – process; primary analysis Source of data for the primary and secondary analyses
Thesis	Secondary analysis, work completed subsequent to implementation and evaluation of the intervention

1.3 Process evaluation of babyClear©

A process evaluation is **"a study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors"** (emphasis added) (Moore *et al.*, 2014, p8). The process evaluation (WP2) reported here, was undertaken as part of a larger, mixed method, evaluation study. WP2 used a prospective, interpretive, qualitative method to explore the perspectives of staff and patients. It took place as the intervention was being implemented. It used a social constructivist epistemology and data were collected through observations and interviews. It was designed to complement the effectiveness and cost-effectiveness evaluations (WP1) and **"to understand implementation, causal mechanisms and the contextual factors which shape outcomes"** (emphasis added) (Moore *et al.*, 2014, p21).

The methods are explained more fully in Chapter 5; however, it is useful to note two points at this stage regarding the evolution of the evaluation process and reporting/dissemination to date:

1. Medical Research Council (MRC) guidance specific to process evaluation was published during the evaluation period (Moore *et al.*, 2014). It sets out the MRC's considered position regarding conducting a process evaluation.
2. Updated MRC guidance on complex interventions is being drafted as this thesis nears completion (Craig *et al.*, 2019).
3. Publication and dissemination
    - Effectiveness and cost-effectiveness evaluation has been published in Tobacco Control, including proxy factors derived from the qualitative data (Bell *et al.*, 2018) (Appendix 11.1.1)
    - Some process evaluation findings have recently been published (Jones *et al.*, 2019) (Appendix 11.1.2).

1.4 Normalisation Process Theory as the lens

This thesis aims to examine NPT and explore how it can be used to support the implementation of complex interventions in ways that maximise their potential. NPT is a theory of implementation; it is designed to investigate the behaviours of actors in a specific environment, and the potential of an intervention for 'workability', 'fit' and integration into current practice i.e. normalisation (May *et al.*, 2007a; May *et al.*, 2007b). It looks at the meso level of context: group interaction and collective working (May and Finch, 2009). NPT is more fully explained in Chapter 3. The theory continues to be developed through the work of the original authors and from the contributions made by other researchers who have used NPT in their own studies (May *et al.*, 2018). Developers of NPT state that "NPT provides a set of sociological tools to understand and explain the **social processes** that frame the implementation of **material practices**" (May and Finch, 2009, p540) (emphasis added). This social context in which the practice takes place, and its profound impact upon real-life, is a key point of interest; both in the literature highlighted in Chapters 2 & 3 and throughout the thesis. The healthcare practice context in which the implementation takes place is also of major interest, as it continues to be highlighted as a critical element in supporting pregnant women to stop smoking (Bauld *et al.*, 2017).

In this thesis NPT is used to frame the implementation process and illuminate its different elements. NPT is used to unearth the linkages that explain the process of normalisation of this new intervention in its organisational context and the challenges of moving theory into practice. As in all process evaluations, the major concerns are to establish feasibility, fidelity and sustainability, and in addition, when using NPT, the potential for normalisation (May *et al.*, 2007b; Moore *et al.*, 2014). These concerns are addressed in this thesis through

applying the NPT core concepts, in the secondary analysis, to the context, hypothesised mechanisms of impact and active ingredients identified from the data.

NPT is a relatively new theory within implementation science; it has been gaining prominence and offers a fresh theoretical framework (May and Finch, 2009; Lynch *et al.*, 2018). Studying NPT offers an opportunity to play a (very small) part in the process of theory development and furthering understanding of implementation processes (Lynch *et al.*, 2018; May *et al.*, 2018). It is timely to consider NPT now, compared to any previous time, as its attributes support developments in the UK MRC guidance for research (Craig *et al.*, 2008; Craig *et al.*, 2009; Moore *et al.*, 2014; Craig *et al.*, 2019). MRC guidance is increasingly supportive of process evaluation and acknowledges the complementarity of different approaches and methods (Craig *et al.*, 2008; Craig *et al.*, 2009; Moore *et al.*, 2014; Craig *et al.*, 2019). As acknowledged by Lynch *et al.* (2018), there is no single or 'correct' approach, method or theory to conducting enquiries into implementation; however, there is an "art" to deciding which to use (p7 of 11).

This study will show for the first time, to my knowledge, that NPT can be used successfully in combination with a logic model (W.K. Kellogg Foundation, 2004). The usefulness of logic modelling in implementation science is already accepted (Lynch *et al.*, 2018). More information on logic modelling can be found in Chapter 2. Furthermore, populations and topics not previously explored using NPT, will be considered and the pioneering journey undertaken to use NPT to understand the intervention's feasibility and fidelity will be described. This was not a straightforward experience and areas where applying NPT created challenges will also be discussed.

Lynch *et al.* (2018) assert that implementation science is still immature and suggest this offers opportunities to "think outside the box" (p6 of 11). Choosing the application of an evolving theory to study is exciting and stimulating (May, 2013b; May *et al.*, 2018). It offered me an opportunity to examine the process of theory development in real-time. It enabled me to gain a deeper understanding of the growing evidence-base and to explore ideas as they happen (MacFarlane and O'Reilly-de Brún, 2012; May, 2013a; May, Johnson and Finch, 2016; May *et al.*, 2018).

1.5 Aim of the thesis

The aim of this thesis is thus **to examine the utility of NPT in understanding the theory-practice gap and the challenges to implementing evidence-based interventions, using the data from implementing babyClear© as an example**. This was achieved by critically examining the capacity of NPT to identify the process by which a specific, evidence-based, health intervention, babyClear©, was assimilated into routine practice, i.e. normalised. This involved understanding the processes that are operating to promote normalisation within a complex intervention and its implementation, and ultimately therefore, the intervention's feasibility, fidelity, sustainability and transferability.

The working assumption when implementing babyClear© was that the intervention could be applied as a standard package across different locations and its effectiveness measured by evaluating this natural experiment. It was assumed that the intervention could (and would) be implemented without deviation or variation.

1.6 Research questions

To meet the aim of the thesis the research questions (RQs) consider: -

1) To what extent does the NPT framework successfully allow:
   a) identification and
   b) elaboration
   of the process of normalisation of a complex intervention?

2) To what extent does the NPT framework assist in understanding:
   a) feasibility and
   b) fidelity
   whilst allowing interventions to be adapted to the needs of the complex systems in which they operate?

3) To what extent does the NPT framework assist in understanding:
   a) sustainability and
   b) transferability when scaling up to population level?

1.7 Plan of the thesis

Tables 1-2, 1-3 and 1-4 offer a guide to the thesis, how the narrative begins, develops, expands and concludes. Due to the origins and conduct of the study, the thesis has been structured unconventionally: the background focuses on the theory and research environment, rather than the usual literature review, because the data collection had already been completed. For similar reasons, reporting the methods of secondary analysis are favoured over those of primary data collection/analysis. It became clear that the context of implementation was paramount, so the analysis begins with a description of the expectations from the intervention and its mechanisms, which then allowed me to compare them with actual staff experience, thus exposing the theory-practice gap to the NPT gaze.

Table 1-2: Plan of the thesis

Part 1 Provides a general introduction, an outline of the relationship of NPT within its theoretical framework, background information on the intervention example, (babyClear©), the current research environment in public health and the theory being studied, Normalisation Process Theory (NPT).	**Chapter 1, Introduction** questions why and how some evidence-based, complex interventions are assimilated into practice while others are neither sustained nor impactful. This theory-practice gap arguably results from an over-reliance on a positivist ontology and epistemology using trial methodologies to study complex, public health interventions. NPT is introduced as a potential theory for investigating this question. The intervention example that provided the data, babyClear©, is introduced and described, as is contextual data around the study setting and population of pregnant smokers.
	Chapter 2, Research Environment situates NPT within its theoretical framework, then tackles how research methodology and conduct in public health is shaped by the academic research environment. It describes the present stage of thinking in which complex interventions, specifically those with a public health focus, are being designed; that is, primarily still within a positivistic worldview. The chapter questions this stance and suggests that new theoretical frameworks and methodologies are required to strengthen the knowledge gained through non-experimental research.
	Chapter 3, Normalisation Process Theory gives an outline of NPT, the theory being examined in this thesis. NPT was developed in response to evidence of a theory-practice gap. It aimed to assist in understanding the process involved when introducing an intervention. NPT focuses on the specific activities required for normalisation. An introduction is given to the important effect of environment and specific contexts on the implementation process, and the attributes of NPT, found in the literature.

Part 2 Explains the philosophical underpinning of the thesis. The details of the method employed during the evaluation (WP2) are also covered in preparation for considering the findings from the secondary analysis.	**Chapter 4, Methodology** puts forward the philosophical base and methodology used for the thesis and explains the underpinning socially constructed ontology and interpretivist epistemology.
	Chapter 5, Method is concerned with the method used for the process evaluation in the example intervention, which is based on the suggestion in Chapter 2, of a constructivist, interpretivist methodology, when evaluating the implementation of complex interventions in public health.

Table 1-3: Plan of the thesis CONTD. 1

Part 3 Outlines the programme theory and consequent choices made for delivering and evaluating babyClear©. It explains the analytical process used in the thesis and collates the data on contexts. It sets out the findings from examining the hypothesised logic model and comparing it with the evaluation data, identifies other active ingredients for the programme theory, not found through trials, and their barriers and facilitators, then moves towards examining the role of these factors during implementation.	**Chapter 6, Exploring the Programme Logic** explains the derivation of the source data and explores the analysis undertaken to elucidate the (otherwise hidden) programme logic behind babyClear©. The information in this chapter will be used to inform Chapters 7 and 8.
	Chapter 7, Analysis and Findings 1 forms the groundwork for answering RQs 1 and 2 by examining the extent to which application of the NPT-derived framework is useful when implementing a complex intervention.
	Chapter 8, Analysis and Findings 2 uses NPT to develop the analysis and answer RQs 1, 2 and 3, i.e. it explores how NPT can be used to bring to light the factors that affect intervention outcomes, but which are neglected in trial methodology - and critiques the findings.

Table 1-4: Plan of the thesis CONTD. 2

Part 4 Discusses the findings and makes clear the contribution to knowledge – and the limitations and strengths of the doctoral study, including its impact to date - then draws the thesis together in the conclusion. It makes recommendations for future use of NPT and suggests areas for theory and application development, research, policy and practice.	**Chapter 9, Discussion** states the key findings then contextualises the chapter in relation to NPT and logic modelling. It considers how the findings support or deviate from the literature and explores, using NPT, how the staff populations in the example are affected, and how the intervention supports pregnant smokers to overcome their specific barriers to quitting. Then it looks at the role of NPT in investigating the implementation process, in the light of the literature.
	Chapter 10, Conclusion, Contribution to Knowledge and Recommendations leads the reader through the thesis' narrative and draws it to a close. Then demonstrates how NPT has been applied in new ways, which advance current practice in three domains: • Theory application • Process evaluation • Clinical situations The chapter ends with making recommendations for future research concerning the implementation of complex public health interventions in general, and babyClear© in particular.

1.8 BabyClear© intervention: context, content and evaluation

1.8.1 Historical context of the intervention

The evidence has long been clear regarding the urgent requirement to address SiP, due to the adverse outcomes for mothers and babies, including miscarriage, premature birth, still birth, neonatal complications, low birth weight, sudden infant death, and ongoing health conditions in the children, including problems of the ear, nose and throat, respiratory disease, and difficulties with attention, hyperactivity and learning (RCG & TAG, 2010; Lowry, Scammell and Challenge Group, 2013; Department of Health and Social Care, 2018a; RCG & TAG, 2018). Smoking is known to be the "greatest modifiable risk for poorer pregnancy outcomes" (NIHR, 2017).

The group of pregnant women who continue to smoke, on the whole, find it more difficult to quit compared to others; they tend to be more highly dependent on nicotine and from the most deprived areas, their pregnancies are more likely to be unplanned, they have low levels of education and health literacy and live in poorer housing, without their spouse/partner; they are characterised by a psychosocial profile of external locus of control, lower self-efficacy/esteem and low mood (Ershoff *et al.*, 1999; Aveyard *et al.*, 2005; Ma *et al.*, 2005; Lawrence and Haslam, 2007; Koshy *et al.*, 2010; El-Mohandes *et al.*, 2011; Prusakowski *et al.*, 2011; Maxson *et al.*, 2012; Chamberlain *et al.*, 2013; Smedberg *et al.*, 2014; Ussher *et al.*, 2016). In addition, multiple studies show that a partner who smokes, multiple children, older age, as well as deficiencies in prenatal care are predictors of smoking during pregnancy (Ma *et al.*, 2005; Hennrikus *et al.*, 2010; Koshy *et al.*, 2010; Schneider *et al.*, 2010; Smedberg *et al.*, 2014).

In contrast to the physical health benefits of quitting, smoking has been shown to be associated with comfort and 'me time' for women who are under stress from their impoverished circumstances (Lumley *et al.*, 2009). For the women who continue to smoke into their pregnancy, they may feel that smoking offers more benefits than quitting (Flemming *et al.*, 2015). In particular, they may be concerned about the stress of withdrawal, and the likely arguments with relatives that would ensue, having a negative effect on the baby (McBride *et al.*, 2004; Lawrence and Haslam, 2007; Flemming *et al.*, 2015). Family and partner relationships may be quite volatile (McLeod *et al.*, 2003; McGowan *et al.*, 2010). It can be imagined, how these factors, often associated with deprived lives, are all interconnected into a web which promotes continued smoking unless 'something' can instigate change.

This finding, concerning the layers of complexity, is important. One aspect of this is the recognition that pregnant women who smoke are in a unique position compared with the smoking population in general (McBride, Emmons and Lipkus, 2003). Alongside this uniqueness there is now an understanding that although there is some overlap with all smokers, their position is different (McBride, Emmons and Lipkus, 2003). This difference has a number of aspects. Primarily there is a new concern by mothers, not just for themselves but for their growing baby (McBride, Emmons and Lipkus, 2003). Their increased contact with HCPs who are raising the issue, highlight their need to be healthy and live long to mother their child, which is at odds with smoking outcomes (Ruggiero *et al.*, 2000; Barker *et al.*, 2002). They may also be keen to avoid the stigma attached to SiP (McBride, Emmons and Lipkus, 2003; Borland *et al.*, 2013; Lupton, 2014). Indeed, many smokers quit just before or early in pregnancy (El-Mohandes *et al.*, 2011; Maxson *et al.*, 2012).

The literature around the life course is very informative in this regard and it does throw some light on the way that these life environments and health inequalities are perpetuated (Barker *et al.*, 2002; Marmot Review Team, 2010; Borland *et al.*, 2013; Marmot, 2015). This is relevant to this thesis in so far as it informs us about the circumstances of these women's lives, and specifically in quitting smoking; and therefore, what any successful intervention must address (McLeod *et al.*, 2003; Joseph *et al.*, 2009; McGowan *et al.*, 2010; Lewis *et al.*, 2016).

Pregnancy creates what has come to be known as 'a teachable moment' in some women, an opportunity when they are more open than usual to public health messages with regard to smoking behaviour (McBride, Emmons and Lipkus, 2003; Lawrence and Haslam, 2007; Mauriello *et al.*, 2011; Galloway, 2012; Maxson *et al.*, 2012). Women spoke about how they wanted to live long and healthy lives for the sake of their children, not just during pregnancy, but into the future for the child (Flemming *et al.*, 2013). It is a time when they are more likely to be motivated to quit, more so than at other times (Aveyard *et al.*, 2005; Crozier *et al.*, 2009; Cluss, Levine and Landsittel, 2011; Maxson *et al.*, 2012).

Lawrence and Haslam (2007) neatly summarise the evidence which recognises the complicated, multifaceted nature of addressing SiP through quitting, the basis of SS interventions in health behaviour theories, and the context of pregnant smokers' lives; including the opportunity of pregnancy as a teachable moment, the influence of partners' smoking status and the contradictory evidence with regards to effectiveness of interventions. These raise many questions relevant to individual women's behaviour change e.g. Does increasing the awareness of risks help? Is the level of staff training adequate? Is the dose sufficient? Would Health Care Professionals (HCPs) gradually distancing themselves at the

end of the quit be better than an abrupt end to support? If women are not quite ready to quit, how is this best dealt with? (Lawrence and Haslam, 2007).

Prior to the babyClear© project, public health guidance had been issued by NICE (PH Guidance 26 (2010; 2013a) and 48 (2013b), outlining the evidence for the actions required by maternity and stop smoking in pregnancy services to address these issues (Appendix 11.2.1). NICE (2010) made eight, broad recommendations, which are included in the babyClear© approach; although the Risk Perception Tool (RPT) is additional (see 1.8.5). Furthermore, national governments had sought to support change in smoking behaviour over the years through the issue of policy documents such as: *Smoking Kills: a white paper on tobacco* (DH, 1998) and *Healthy lives, healthy people: a tobacco control plan for England* (DH, 2011a). During the period of the evaluation, a major report was published by organisations represented by the Challenge Group (Lowry, Scammell and Challenge Group, 2013), a partnership between professional bodies, the voluntary sector and academia, including Action on Smoking and Health (ASH), Lullaby Trust, Faculty of Public Health, Royal College of Midwives (RCM) and many more concerned bodies. Entitled, '*A call to action*,' it was written as a battle cry, to stir up those in government and local health services to fund and implement services and initiatives to bring down rates of SiP (Lowry, Scammell and Challenge Group, 2013). Work was also being carried out by NHS England (NHSE) on new guidance for midwives: *Saving Babies Lives: Reducing Stillbirth and neonatal death: A care bundle* (2014) which strongly endorsed stopping smoking in pregnancy. Indeed, the guidance is in line with midwives' public health role (Marshall and Raynor, 2014).

NHSE has shown ongoing commitment to supporting patients in changing unhealthy behaviours e.g. in Commitment 6 of its strategy: *Leading Change, Adding Value: a framework for nursing, midwifery and care staff*, where it outlines its desired direction of travel for the nursing and midwifery professions (2016, p25). In 2017, the government updated its policies on smoking and published *Towards a Smokefree Generation: Tobacco Control Plan for England 2017-22* (DH, 2017), with the 'ambitious new goal' of 'reducing the prevalence of smoking in pregnancy from 10.7% to 6% or less by the end of 2022' (p10). The Department for Health and Social Care subsequently published the *Tobacco Control Plan: Delivery Plan 2017 – 2022* (DHSC, 2018a) to monitor progress, then the NHSE published the government's NHS Long Term Plan in January 2019 with a stated focus on primary care and prevention, including cutting SiP (Summary, Chapters 1 & 2, p6, 7).

The pressure from national organisations continues: The Challenge Group have published an update to their 'Call to Action' (2013) entitled, *Review of the Challenge* (2018) which

takes the view that the government will miss its target for reducing SiP unless more is done. Another update by the RCP, *Hiding in Plain Sight: Treating tobacco dependency in the NHS* (2018), re-states very clearly the urgent need to address SiP to reduce related, adverse health outcomes for mother and baby. In this way, continuous pressure from major stakeholders has been applied to the national government and commissioners of maternity and stop smoking in pregnancy services, to focus on supporting pregnant women to quit smoking.

1.8.2 Geographical and regional context of the implementation

The geographical area of interest for the implementation, NE England, is a region in economic decline; with high levels of deprivation, unemployment and lives lived with multiple, disadvantaging, socio-economic and environmental factors (Ministry of Housing Communities and Local Government (MHCLG), 2019).This is reflected in the Index of Multiple Deprivation (IMD). The IMD is used as an indicator of deprivation; it combines various measures to give an overall figure for local areas, called Lower layer Super Output Areas (LSOAs) (n=34 753) (MHCLG, 2019). LSOAs are designed each to contain similar-size, human populations. They allow for statistical comparison of deprivation between areas. So, for example, in 2019, Mole Valley District Council in South East England, had 56% of its LSOAs in the 10th IMD decile i.e. least deprived, compared with Middlesbrough, a Unitary Council in the NE, which had the complete opposite with 51% in the 1st IMD decile i.e. most deprived.

Table 1-5: Comparison of deprivation between English councils

Council	**IMD decile**									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Middlesbrough (Unitary)	47	7	6	4	3	3	7	8	5	1
Sunderland (City)	42	33	24	22	16	9	15	16	7	1
Newcastle (City)	37	21	9	9	12	11	6	9	12	14
Northumberland (County)	23	17	18	22	22	22	20	12	21	19
Mole Valley (District)	0	0	0	1	0	2	2	1	5	14
Surrey (County)	237	137	101	73	56	43	41	15	4	0

Taken from Ministry of Housing Communities and Local Government (2019).
IMD decile 1: most deprived; IMD decile 10: least deprived.

It should be noted that within the NE region there are areas with less deprivation; however, the number of highly deprived areas is far greater compared to other areas in England (see Table 1-5). Historically, deprivation is associated with unhealthy lives, including high rates of smoking; which in turn produce raised SATOD rates compared to more socio-economically advantaged areas (see Table 1-6). The SATOD rate in NE England is persistently higher than the national average, and prior to the commencement of the primary study in 2012, was around 20%.

Table 1-6: Selected Smoking at Time of Delivery rates across England 2010 - 2018

Area	**Dates**		
	2010/11	**2014/15**	**2018/19**
England	13.6 (19.8)	11.7 (16.9)	10.6 (14.4)
	2012	**2015**	**2018**
NE region	21.1 (22.0)	18.0 (16.9)	15.7 (14.4)
SE region	11.9 (17.9)	10.4 (15.9)	9.7 (12.9)
	2011	**2015**	**2018**
Middlesbrough	27.2 (25.2)	23.1 (20.8)	19.3 (17.4)
Sunderland	21.8 (24.3)	19.4 (21.5)	17.5 (20.2)
Newcastle	18.0 (23.0)	14.7 (18.6)	13.4 (16.0)
Northumberland	20.6 (16.0)	14.2 (16.9)	13.6 (12.1)
Mole Valley	5.6 (12.9)	4.4 (13.3)	5.0 (8.0)
Surrey	7.7(14.9)	6.5 (14.0)	6.1 (10.2)

Taken from Public Health England (PHE, 2019)
Proportion - %; Adult smoking prevalence in brackets.
Please note that there is some variation in dates within reported data.

The NE Strategic Health Authority (SHA), the responsible regional body at the time of the study inception (abolished in 2013), had both a political remit to implement and standardise change across the NE, and was prepared to provide some funding for the regional implementation of an intervention to address SiP (NHS, 2016; Milne and White, 2019).

Fresh NE, the regional tobacco control programme, was prepared to support the intervention and the NIHR (School for Public Health Research (SPHR)) agreed to fund the evaluation. This serendipitous conjunction of events enabled the intervention development, practice rollout and academic research to take place contemporaneously. The funding from the NE SHA and Fresh NE, for carbon monoxide (CO) analysers, training costs and other

disposables, which would have been expected to be covered by the Trusts in a nationally, peer-reviewed study like this, “removed a potential financial dispute, allowing assessment of the intervention against a more neutral managerial background” (Milne and White, 2019).

NICE PH Guidance (2010) already gave responsibility to the maternity services to offer brief SS advice to pregnant women and had also recommended universal, CO monitoring. However, whilst there was awareness about these issues, it cannot be assumed that maternity and local SSPS incorporated all the NICE PH Guidance (2013b) into their policies and practices (Beenstock *et al.*, 2012; Lorencatto, West and Michie, 2012). Specifically, work by Beenstock *et al.* (2012) highlighted some of the ‘perceived implementation difficulties’ for midwives (NICE, 2010).

Just to note, this preparation period for the study was prior to the rise in use of electronic cigarettes and acceptance by authorities in the United Kingdom, such as ASH, PHE, Royal College of General Practitioners (RCGP) and Cancer Research UK (CRUK), in terms of their value in reducing harm (Britton and Bogdanovica, 2014; McNeill *et al.*, 2015; ASH, 2016; RCGP & CRUK, 2017). Therefore, electronic cigarettes are not considered as a harm reduction or quitting tool in this thesis.

1.8.3 Origin of the evaluation

BabyClear© had not been widely studied (Fendall *et al.*, 2012) and its introduction across a regional setting provided the opportunity for a natural experiment. Natural experiments are sometimes considered the ‘next-best-thing’ to a randomised controlled trial (RCT) in the view of many public health researchers, who would still prefer to conduct a trial (Craig *et al.*, 2009). They take advantage of natural circumstances, where a change occurs across a population, and design a study – based as closely as possible on trial principles - around it (Moore *et al.*, 2014). Commonly, because the context for a natural experiment was not set up for research purposes, the trial methods must be adapted, while keeping as closely as possible to the RCT standard (Craig *et al.*, 2009; Moore *et al.*, 2014). This often means using statistical methods e.g. a cluster-randomised or stepped-wedge design, instead of complete randomisation or controlling, to establish effectiveness and cost-effectiveness (Craig *et al.*, 2008). Evaluating the process might be an integrated or separate strand to the study; in this case it was not integrated.

Fresh NE, the regional tobacco control programme, sought and found a package of measures, babyClear©, from the Tobacco Control Collaborating Centre, to address the

issues around SiP (Beenstock *et al.*, 2012; Fendall *et al.*, 2012). BabyClear© was pragmatically-driven, derived from clinical practice by public health midwives and intended to fill a perceived need (Fendall *et al.*, 2012). It was an innovative package of measures that also offered a structured way to embed NICE PH Guidance (2010) which was itself based largely on trials evidence (Fendall *et al.*, 2012).

The key elements were:

- Standardising CO monitoring of all pregnant women – at the earliest opportunity all pregnant women were to be asked to blow into a CO analyser and the results documented and entered onto a database.
- Opt-out referral of women smokers to SSPS – all pregnant women with a raised CO reading to be automatically referred to the SSS for follow-up, unless they specifically opted-out.
- Enhanced follow up by maternity and SS services – after registering a raised CO reading, women will be referred and contacted quickly and repeatedly, according to a specific protocol. Midwives will monitor CO of pregnant smokers at all antenatal appointments. They will refer them back to the SSS if they have not engaged. SSS will contact them quickly and repeatedly, including immediately after the RPT. Various additional options for follow up might be offered.
- Introduction of a risk perception tool (RPT) – a new tool to be shown by a midwife to pregnant women who, for whatever reason, continued to smoke and had not engaged with SSPS by the end of the first trimester (12 weeks gestation) to persuade them to quit (see 1.8.5 for more details).

The measures were designed to work together in one pathway (Table 1-7) to promote stopping smoking in pregnancy. With the exception of the RPT, these were not entirely new measures; however, they aimed to remove any barriers and create systems that enabled HCPs to carry them out. Local Trusts and SSS areas were expected to work together, with the training organisation and Fresh, to bring their services in line with the intervention. It was anticipated that SATOD rates could be reduced by prioritising this topic, raising awareness and skills through training, and implementing system changes according to the babyClear© pathway. Key to success was the integration of maternity and SS service delivery.

Table 1-7: BabyClear© pathway

Steps	Timing	Action	By Whom
1	At booking	Carbon monoxide (CO) monitoring of all pregnant women (integrated within routine care)	Midwifery Team
2	Within one working day of CO monitoring	Send all CO monitoring forms to SSPS* by fax/email	Midwifery Team
3	Within two working days of receiving referral at SSPS	Telephone call from service provider offering appointment, if not arranged by midwifery team earlier. Midwife informed if service declined and letter sent offering support.	SSPS
4	Within five working days of Step Three	Face to face contact with Stop Smoking Advisor to undertake assessment and give support. Contact as agreed if does not attend (DNA). Midwife informed if no further appointment plus letter to woman offering support.	SSPS
5	First scan appointment	Risk Perception Tool for those not engaged with SSPS and record in midwifery notes, including outcome. Offer another referral to SSPS.	Specialist Midwife
6	Future antenatal appointments	CO monitor and re refer pregnant smokers who have not engaged with SSPS.	Midwifery Team
7	10 - 14 working days after referral to SSPS	Telephone call to pregnant smoker asking if referral satisfactory. If not or no contact with service offer other options.	SSPS
8	Monthly follow up during pregnancy	Telephone call to pregnant smoker asking if service is satisfactory and if any further help is required OR If agreed at Step Three/Four a call to women who refused service to reoffer support.	SSPS
9	Status at delivery	Smoking status collected by Midwifery Service. All women who smoke reoffered support.	Midwifery Service SSPS
10	On discharge from midwifery care	Health Visiting Service advised of smoking status.	Midwife using handover notes

* Stop smoking in pregnancy services

At this stage it may be helpful to clarify the terms Stop Smoking Service (SSS) and Stop Smoking in Pregnancy Service (SSPS) as they are subtly different. SSS refers to publicly funded, generic, free to access, Stop Smoking Services for all smokers. It is the responsibility of the local authority (LA) to provide these services. They also see smokers who are pregnant. Depending on the local service delivery model they sometimes offer a specialist pregnancy service. SSPS refers to stop smoking services specifically for pregnant women, this includes elements of maternity services and the provider model that has been agreed. This may be entirely within maternity services or include elements of SSS too (see Chapter 7).

1.8.4 Pre-implementation phase

Discussions were held between providers of the intervention and senior managers in each Trust. The aim was to work out how the implementation would move forward and to gain permission for the evaluation. A series of training sessions were then planned for the region. They included four types, varying in length from 2 hours to 2 days, aimed at different roles (see 5.3.1 for details of training sessions). They were held at focal points across the region, requiring employees from different organisations to travel to the site.

Although it was not apparent at the outset, each LA had a different service delivery model (SDM) and so did each maternity service. Combined, this created five different SDMs; although provision standards should be the same, including three levels of qualification for providers: Tier 1 – provide a brief intervention only; Tier 2 - general SSS provision; Tier 3 – specialist SSS provision, including pregnancy. This study is interested in looking at how using NPT supports understanding each context and its effect on normalisation. A description of each Trust follows, as the differences create unique contexts for the implementation, which in turn create particular barriers and facilitators.

Trust A

This Trust covered both urban and rural areas. It had two consultant-led and two midwifery-led, maternity units. Trust A and C had overlapping LA boundaries meaning that they both had some responsibility for patients who lived in some Trust A areas but were delivered in a Trust C hospital. This is further complicated by some patients choosing to deliver out of their living area, for example travelling to a hospital in Trust B or H. The Trust had no early bird session and offered a standard approach from both services. This changed when, in anticipation of babyClear©, some maternity care assistants (MCAs) were introduced (like

those already established in Trust C) and a stop smoking champion was appointed, who bridged maternity and SSP services.

Trust B

This Trust, along with Trusts F and G, was relatively small, with one consultant-led unit. Their LAs worked together and provided the unusual hub, mentor, multiple-provider model. Trust B differed though, in that as well as a public health midwife it had a team of ten MCAs. They worked in the community and answered to the public health midwife; their specific responsibility was breastfeeding and focused on mothers aged under 25, however stop smoking was added to their remit. Like in Trust A, they followed up pregnant smokers in their homes, alongside and in addition to, breastfeeding support. The public health midwife was the champion for babyClear© within the Trust and was in regular communication with the SS mentor.

Trust C

This Trust was relatively small and covered a largely urban area, with two towns where hospital maternity care was offered; one consultant-led and one midwifery-led. Maternity services had some responsibility for patients who lived out of area, but were delivered within area, because the LA was not co-terminous with health Trusts. Trust A supplied SSPS to these patients in the community but area C provided the RPT. Usually, when a woman had been to see her General Practitioner (GP) with a positive pregnancy test and was referred to the midwifery team, this referral was picked up by MCAs. A pre-booking system, sometimes called an early bird session, was promoted in this Trust. The MCAs contacted the woman to arrange a pre-booking appointment, and during this initial call, asked if she smoked. If she said she was a smoker the MCAs offered to visit her at home or follow her up at pre-booking. At this pre-booking session many public health messages and information on the tests available during her pregnancy were given. Most women who attended early bird sessions were around 6 weeks pregnant. A CO reading was taken, advice offered, home visits and Nicotine Replacement Therapy (NRT) vouchers arranged. Booking-in was at around 8 weeks. For those who had not attended pre-booking, the SS messages and CO monitoring was carried out at this point. The midwife would reinforce the SS message. Women with a raised CO were referred to the MCAs, who did most of the follow up work for stop smoking. The next CO reading by the midwife was taken at 28 weeks.

Trust D

This Trust covered both urban and rural areas and had one, regional centre for healthcare, with another smaller, consultant-led unit. Although not in a city, and less specialist than Trust

H, it similarly experienced more complexity. Early bird sessions were offered, and the SS journey begins here with the midwife. There were MCAs but none with a SS remit. Along with Trusts C and B, this Trust had an established public health midwife, but unlike them it had multiple consultant clinics for high-risk cases. Up until March 2014, the SSPS had an administrative centre and ran a specialist team offering community drop-ins and clinics, although only some areas were covered. Some Healthy Living Pharmacies (HLPs) were Tier 3 providers too - the idea was that pregnant women could access a full, intermediate assessment, receive ongoing support for 12 weeks, and experience a one-stop service for both medication and support. HLPs were a relatively new initiative and the process for commissioning them was changing with the demise of Primary Care Trusts (PCTs). The new Clinical Commissioning Groups (CCGs) decided that no more pharmacies or GP surgeries would be funded to provide a Tier 3 service in the LA area. By mid-November 2014 the new manager still had not been able to talk to the CCG about the withdrawal of provision of funding for Tier 3 providers in the community, despite many attempts.

Going forward though, the SSS that had been inherited from the PCT and was now run by the LA, was to go out to tender when the contract ended on March 31st 2014. Throughout the time of the introduction of babyClear© all SSS specialists knew that this would be happening and were living with a high level of uncertainty over their job security. Training continued regardless but the outcome remained unknown i.e. who will win the contract and what the service delivery model would be. They had just been told unofficially at the time of interview in February 2014 i.e. with only 6 weeks to go, that they had lost the contract and that it was going to Trust C. Some people had already left to find other jobs, some hoped to be 'TUPEd' over.

SSS staff expressed concern that they did not have sufficient capacity due to low staffing levels, if many more clients came through, as expected from the intervention. They accepted their last client in December 2013, as they were not clear if they would be able to complete the 12-week treatment programme. The new contract started in April 2014. The manager of the new service was appointed in September 2014 and started on 1st October. After many months of uncertainty and lack of leadership new services were set up, however these fell outside the time of data collection for the evaluation.

Trust E

This Trust covered a few urban, but mostly scattered, rural populations, which brought specific challenges. It had one consultant-led unit and four midwifery-led. Sometimes people on the boundaries accessed care from other Trust areas which were closer to home. There

was limited access to the internet when HCPs were out and about, reducing the benefits of inputting to Quit Manager™, or similar, when off-site. There was no public health midwife or any MCAs with a health promotion/stop smoking role in this Trust. Instead the SSP specialist from the service had spent time liaising with maternity services to promote the stop smoking agenda. No early bird/pre-booking session was offered in the rural areas, but it was available in urban areas.

Trust F & G

These two Trusts, along with Trust B, were relatively small, meaning that each one had less flexibility in terms of resources and economies of scale. Trusts F, G covered urban areas adjoining a city, each with one consultant-led unit. Many of their pregnant women attended the city hospital, depriving them of funds, but still using their community services. Their Las, with Trust B's, had banded together to provide a SS service, using one SDM from January 2013, provided by Trust A (see Trust B for their different approach in maternity services). These LAs had chosen a non-specialist SSP service delivery model, which replaced a specialist model. It involved a central office, known as the hub, from which the service was managed. The SSPS administration staff and mentors sat within the hub. A mentor had responsibility for an area in terms of identifying providers, ensuring they were trained and updated and communicating with maternity services to review any issues. The providers of stop smoking advice and treatment were within the community setting and called active intervention (AI) providers. They included GP surgeries, pharmacies and children's centres, where staff in multiple organisations could offer to provide this service e.g. health trainers, youth workers etc. All providers were trained to give advice to all groups, including pregnant women. Initial contact with the SS service was via a midwife at booking-in and all three Trusts (F, G, B) had public health midwives with responsibility for the SS agenda. Pregnant smokers could also sign up to 'Florence', the text messaging service. This was an automated service which sent various myth-busting facts, with occasional requests to text back.

Trust H

This Trust covered an urban area with one, large, maternity centre, drawing patients from a wide area through patient choice, but also including all high-risk patients for the region. There was no public health midwife or any MCAS with a health promotion/stop smoking role in this Trust. Initial contact for pregnant smokers was at booking-in with the midwife. The SSPS had undergone severe restructuring over the last couple of years. It now only covered the city; whereas previously it served neighbouring areas too. Reorganisation and rumours of re-tendering had resulted in significantly lower numbers of staff remaining; both

administrative and advisory. Technically this remained a pregnancy specialist service, however the experienced SS pregnancy advisors had left. Their role was taken up by a Nurse Specialist Stop Smoking Advisor, who focused on various groups of clients and had begun to see pregnant women as well. She was responsible for midwives' training and ensuring compliance with NICE PH Guidance (2010).

Trust J

This Trust and LA area was adjacent to Trust H and received their SSPS provision from them until they split away in early 2014. In January 2014 the SSPS stopped taking on new clients as part of their exit strategy. Pregnant smokers were referred to community providers with little experience of pregnancy challenges for a time. There were concerns about quality of provision from the start of 2014. From April 2014, a new SDM that had not been tried before was to be begin: pregnant women would be referred into a small team of public health nurses, who were experienced advisers. However, they had not worked with pregnant women before.

1.8.5 Changes to usual practice

There were several changes to normal practice associated with introducing babyClear© (Table 1-8). The intervention was required to integrate into existing maternity and stop smoking in pregnancy services' pathways and systems. A description of each of the distinctive procedures within the package, which were changes and additions to usual practice, follows:

Table 1-8: Principal changes and additions to usual practice

Procedure in SSPS* pathway	**Change to procedure**
Universal monitoring of carbon monoxide (CO)	Measures taken to ensure monitoring became universal e.g. appropriate staff provided with sufficient numbers of good quality CO analysers
CO threshold for referral	CO threshold stipulated and lowered
Opt-out referral	Pregnant women required to specifically opt-out
Language of concern	Motivational interviewing techniques built upon, moving further towards empathy and concern
Quitting completely	Cutting down no longer acceptable
Speed of contact from SSPS	Short timeframes ensured quicker follow-up

Increased contact from SSPS	Systematic and frequent attempts at contact
Risk Perception Tool (RPT)	Visual tool to highlight the personal risks of continued smoking carried out by midwife
Data management	Electronic online software recommended

* Stop Smoking in Pregnancy Services

Universal monitoring

A biochemical test of exhaled gases is used to check the pregnant woman's level of CO, avoiding reliance on self-report (NICE, 2010). Inhaling CO can be life threatening to mother and baby as it blocks uptake of oxygen by the body's cells (RCP & TAG, 2010). Specifically, the baby's development can be adversely affected (RCP & TAG, 2010). Raised CO levels indicate smoking or having spent time in an environment with increased CO (RCP & TAG, 2010). This might be due to reasons other than smoking e.g. faulty boiler, car exhaust fumes or second-hand smoke (NICE, 2010). These levels can be monitored by blowing into a handheld analyser (NICE, 2010).

The CO analysers were specific to pregnancy and included the baby's reading in CO parts per million (ppm) and % fetal CO in haemoglobin. They were designed to be easier to use and more appealing to women, with a visual traffic light display and alarm warning when excessively high. Maternity staff each received a new CO analyser at the end of their training session. Chosen to be an improvement on previous analysers; they were registered to staff individually, so they were no longer shared.

The package required the initial referral to be made within 1 working day of CO monitoring. It aimed to be quicker and often earlier in pregnancy than previously, depending on the service delivery model. The standard requirement was referral at the booking-in appointment with the midwife. SSPS required maternity staff to record the woman's reading as well as state if they were a smoker/non-smoker, so the approach to the woman could be tailored appropriately.

Lower threshold

The CO threshold for referral recommended in NICE PH Guidance (2010) offers a range, from 6 – 10 ppm (p6). It was left vague as to how HCPs were expected to apply it. With the intervention, no range was given, instead a specific cut-off was introduced, which was lower than in the guidance, at 4 ppm – and so would include anyone whose levels were only slightly raised.

Opt-out referral

The package changed the procedure from being opt-in to universal opt-out, maternity staff were to refer all pregnant women with a raised CO reading to the SSPS, regardless of smoking status. Smoking was re-phrased as a health condition that required monitoring and treating. Previously, reluctant quitters and those reporting themselves as non-smokers would not have been referred to SSPS, but with opt-out referral almost all smokers and some non-smokers were referred. Opt-out referral, plus the inclusion of all with a raised CO reading, led to a large increase in referral numbers.

Motivational Interviewing

To encourage pregnant smokers to change their behaviour HCPs used motivational interviewing. Motivational interviewing was already well-established and was taught in generic stop smoking advisor training but was also incorporated into the intervention's training. It could be used in face-to-face appointments or over the telephone.

Quitting completely

One of the measures within the babyClear© package was to change the advice previously given by maternity staff, which accepted harm reduction i.e. cutting down, to a complete quit only. For many of the pregnant women, this was in the context of lives associated with deprivation. Often there were many structural and personal issues that impacted upon these smokers, which were integrated with their smoking habits. For example: smoking was described as a coping mechanism that was integral to women's lives, and staff reported that women lacked confidence in quitting successfully. It was reported that a time of emotional stability (which these women may not have) was required for a quit attempt.

Speed of referral

The package introduced quicker and stricter timeframes i.e. referral form faxed/emailed to SSPS within 1 working day; contact attempted by SSPS within 2 working days of receiving the form and an appointment offered within the next 5 days. To receive Nicotine Replacement Therapy (NRT) the smoker required a stop smoking assessment and a prescription to take to a pharmacy included in the local SSPS.

Increased contact

The standard follow-up on referral included up to three telephone calls to the woman then, if unsuccessful in making contact, an information pack was sent out. In addition, the babyClear© package increased opportunities for contact in three ways. Firstly, re-referral at future maternity visits, if appropriate. Secondly, 10-14 working days after referral to the

SSPS, a telephone call was made to the pregnant smoker asking if the referral was satisfactory; if it was not, or there had been no contact with the SSPS, further support and other options were offered. Thirdly, monthly follow up calls continued throughout pregnancy. Referral forms asked for more detailed information than formerly to increase the likelihood of successful contact e.g. mobile and landline numbers, best time to call, acceptance of text and voicemail, and to let smokers know that notifications will use a withheld number.

Risk Perception Tool

The RPT used visual, auditory and tactile media, as well as verbal, to communicate the stop smoking message. The midwife held a life-like, fetal doll, with umbilical cord and amniotic sac. As she explained the effects of smoking, she would demonstrate them on the doll. She would personalise it and talk about "your baby". Then the pregnant woman was asked to blow into a CO analyser. This was connected to a computer and the results were displayed on a screen as the picture of a baby. Depending on the level of CO, the baby may be green, amber or red, even flashing and alarming if it was dangerously high. The mother's and baby's CO readings were displayed. All the while the midwife is explaining what this means for the baby and the mother. The intervention package gave smokers an opportunity to be followed up swiftly by the SSPS after the RPT. The RPT was delivered by a midwife and was an additional procedure to those recommended in NICE PH Guidance (2010). It had not previously been evaluated. Primary analysis revealed how the topic of risk from smoking was introduced was found to be important in bringing the pregnant woman on-side. The RPT was designed by Fendall *et al.* (2012) to reinforce the principles of existing practice, and use the language of understanding and concern, with seriousness and authenticity, then offer a further opportunity to engage with SSPS.

Data management

An efficient data management system was required to ensure that the pregnant woman's interactions with SSPS were captured; including provision of advice, CO monitoring, take-up of NRT, setting a quit date, changes to smoking status, support and contact offered and received. An important reason for using an accredited system was to ensure that it provided a high standard of data capture and facilitated data management. This would then equip HCPs with up-to-date information on the woman's latest engagement with services as well as meet the statutory requirement for data submission e.g. national standards for SSS data, Trust Commissioning for Quality and Innovation (CQUIN) data. The contractors who supplied babyClear© recommended the use of Quit Manager® (2019) or similar. Quit Manager® is an electronic, online system designed for supporting SSPS with their data management.

1.8.6 Pregnant woman's journey

This section offers an opportunity to see the package of measures from the perspective of the recipient (Table 1-9). Every pregnant woman is assessed to see if she is a candidate for referral to SSPS.

Table 1-9: Pregnant smoker's journey

Steps	Timing	Action	By whom
1	At first contact /appointment with maternity services	Carbon monoxide (CO) measured If over 4 parts per million referred to SSPS* unless opts out	Midwife or maternity care assistant
2	Within 2 days of step one	Receive a call regarding follow up by SSPS Offered an appointment/visit	SSPS member of staff
3	Within 5 days of step two	See a stop smoking advisor CO measured Assessed for support Offered assistance e.g. nicotine replacement therapy (NRT), personal support and advice	SSPS member of staff or other role as per service delivery model e.g. maternity care assistant, pharmacist
4	Weekly support for 12 weeks/ until end of pregnancy	Followed up by stop smoking advisor CO measured Continued NRT and support	SSPS member of staff or other role as per service delivery model e.g. maternity care assistant, pharmacist
If pregnant woman does not engage with SSPS at Step 1			
5	Initiated within 2 days of step one	Multiple attempts at contact by telephone Receive a letter if no contact made	SSPS member of staff
6	Within 5 days of step two	If woman does not attend appointment she will receive further attempts to contact and re-refer her by telephone	SSPS member of staff
7	At dating scan (10-12 weeks pregnant)	Risk Perception Tool CO measured	Midwife
8	Maternity appointment, following lack of engagement at steps 5, 6 and 7	Concern expressed at her lack of engagement with SSPS and offer to re-refer her for support to quit CO measured	Midwife or maternity care assistant

* Stop Smoking in Pregnancy Services

1.9 Conclusion

The evidence has long been clear regarding the urgent requirement to address SiP. The need for action was particularly insistent in NE England, which had comparatively high SATOD rates and associated poor health outcomes. The babyClear© intervention, based on NICE PH Guidance (2010), was introduced in this region in response to a government drive to improve maternal and perinatal outcomes. Its roll-out formed a natural experiment which offered an opportunity for an evaluation to be undertaken. This chapter has set out the intervention package – babyClear©. The evaluation of the implementation of babyClear© provides the data for the secondary analysis completed for the thesis and allows for exploration of the theory-practice gap.

1.10 Chapter summary

This chapter has set the scene by explaining the origin of the research questions and how the thesis relates to the overall, initial, mixed methods evaluation. Specifically, the process evaluation, WP2, as it relates to this study is outlined. The basis of the theory, NPT, that is to be examined for its utility, is mentioned, and what it means to use it as the lens for this study is explained. The thesis' aim, scope and research questions are introduced; followed by a plan of the thesis, including a thumbnail sketch of each chapter. Then the background to the intervention is described, as are the pre-implementation preparation and process evaluation that took place. It also outlines the changes to normal practice associated with introducing the babyClear© package and the resultant changes for staff as well as recipients.

Chapter 2 RESEARCH ENVIRONMENT

2.1 Introduction

In this chapter I consider the interplay between the theoretical framework, research environment and evaluation of the implementation of complex interventions. I explore how research methodology and conduct is shaped not only by the intervention itself but also by theory and the academic research environment. I explain the contextual background to the development of NPT and introduce the present stage of thinking in which complex interventions, specifically those with a public health focus, are being contemplated; that is, primarily still within a positivistic worldview.

I start by describing the relationship of NPT within its theoretical framework, then consider the history, development and current debate over evaluation of complex interventions. I note the dominance of the experimentalist approach and the challenge to its assumptions that the evaluation study of the public health intervention under discussion represents (MRC, 2000; Blamey and Mackenzie, 2007; Craig *et al.*, 2008; Moore *et al.*, 2014). I question this positivist stance and suggest that new theoretical frameworks and methodologies are required to use the knowledge gained through non-experimental research. I respond to an exclusively, experimentalist viewpoint, a journey which takes me towards favouring methodologies which collect the relevant data to answer different research questions to understand the theory-practice gap. I comment on the role of process evaluation methodology, most notably in MRC guidance (Moore *et al.*, 2014). I reflect on the shift in academic perception towards including interpretive approaches and the application of these methodologies with a new confidence, sometimes in parallel with experimental designs (O'Cathain *et al.*, 2013; Moore *et al.*, 2014; Craig *et al.*, 2019). I finish with a comment on how the research environment has affected the study design of the intervention evaluation and call for a more balanced approach to evaluation study design.

2.2 Relationship to the theoretical framework

Knowing the underlying theory, and its relationship to other theories in the field, is important and thinking through the theoretical basis of a study as early as possible is vital (Stewart and Klein, 2015). Although evaluation studies are all in some way attempting to understand the theory-practice gap, the number of available theories makes it challenging for clinicians and researchers to choose them appropriately (Stewart and Klein, 2015; Lynch *et al.*, 2018). To overcome this unsatisfactory situation a thorough knowledge of the various, relevant theories that have emerged to inform process evaluation is required (Stewart and Klein, 2015).

NPT was identified by the study designers as an appropriate framework to explore the process of implementation of this complex public health intervention because they wanted to understand how it was normalised. This thesis aims to examine how well NPT does this i.e. the utility of NPT in understanding the theory-practice gap and the challenges to implementing evidence-based interventions, using the study example. This required using the constructs within NPT as the lens (see Chapter 3).

NPT draws heavily upon Diffusion of Innovations Theory (Rogers, 2003; May, 2006). Rogers (2003) theorised that there were four stages in the process of diffusion of an innovation: "i) an innovation ii) is communicated through certain channels iii) over time iv) among the members of a social system" (p11). Characteristics of a new idea or practice were hypothesised to affect uptake across an organisation, as was the nature of the existing communication system or 'networks' (Rogers, 2003). In general, Rogers asserts, that interpersonal channels across social networks with homophilous peers were most effective (2003). However, to improve the flow of adoption there was a need for change agents i.e. other, different people, to intervene (Rogers, 2003). The time it takes for the decision to become adopted or rejected was an important dimension and five categories of adopter were identified: (1) innovators, (2) early adopters, (3) early majority, (4) late majority, and (5) laggards (Rogers, 2003). The original diffusion research was carried out in 1903 by the French sociologist Gabriel Tarde, who plotted an S-shaped diffusion curve (uptake plotted cumulatively against time); that is diffusion starts off slowly within the group (1), then more join (2), groups (3) and (4) join in and then the final group (5) joins in as uptake tails off (Rogers, 2003). Rogers (2003) suggested that the structure of the social system also affected diffusion, for example the social norms and role of opinion leaders.

Greenhalgh *et al.* (2004) in their extensive, influential, meta-narrative review of innovation in service delivery and organisation, built on the work of Rogers (2003) and others. Their main aim was to discover how to "spread and sustain innovations in health service delivery and organisation"; diffusion was defined as passive spread (Greenhalgh *et al.*, 2004, p581). This was achieved by unearthing the storyline of the development over time of ideas, theories and methods that were interested in planned, co-ordinated innovation in service delivery and organisation and directed at improving health outcomes, administrative efficiency, cost-effectiveness or users' experiences (Greenhalgh *et al.*, 2004). The importance of organisational culture, attitudes to change and other contextual conditions, on the adoption of service innovations was highlighted (Greenhalgh *et al.*, 2004). These highly influential factors cannot be fully accounted for in trials, which are principally quantitatively driven and

work within a fixed structure (Tansella and Thornicroft, 2009; Moore *et al.*, 2014). This viewpoint is only now becoming more fully accepted (Craig *et al.*, 2019).

The theoretical framework is required to work at several levels; most obviously in this study at the individual, group and institutional. Regarding staff, behaviour relying on entrenched beliefs (internal) and systems (external) is required to change if the intervention is to be effective (NICE, 2010). In a relativist ontology the self is socially constructed through experience; while this offers the opportunity for personal behaviour change one may yet be constrained by external structures (Annandale, 1998). Relativist ontologies require interpretive methodologies but, in health research, the established methodology for assessing the value, effectiveness and success of an intervention has been the use of trials and systematic reviews of trials (e.g. Cochrane Reviews, Health Technology Assessments) (MRC, 2000) (see 4.2.1).

2.3 Experimental methodologies

The focus of any trial is to determine causal attribution by linking cause and effect, principally doing this by attempting to exclude contextual confounders (MRC, 2000; May, Johnson and Finch, 2016; Connelly and Vanderhoven, 2018). A trial usually has several key design features (see Table 2-1).

Table 2-1: Key features of experimental or trial designs

Feature	**Benefit**
Objective	Unbiased by researchers or participants
Laboratory-based	Constant controlled environment without variation
Randomised and controlled	Groups are identified randomly Bias is limited by the methods e.g. homogenous groups are compared in heterogeneous settings/conditions of interest Control groups are used to allow for variation in the calculations
Rigour	Rigorous methods are employed to ensure experiments are replicable and generalisable
Primarily use quantitative methods e.g. numerical records, to produce experimental data i.e. numerical or statistical format	Outcomes are quantifiable

(MRC, 2000)

Experimental methodologies have been developed over many years and have become established at the top of the hierarchy of designs (MRC, 2000; Connelly and Vanderhoven, 2018). The trial of a drug versus a placebo is a good example of an intervention that is appropriate for an experimental design (MRC, 2000). The research questions are likely to be: Does this drug work? If so, how effective is it? Are there any side effects? How much should be given? How often? If necessary, different elements of the intervention can be separated out and tested for effectiveness or tried in combination to find out what works well (MRC, 2000). Experimental designs are very useful when identifying causal relationships and deciding if an intervention is effective and/or cost-effective, when the requirements for randomisation, controlling and easily quantifiable outcomes can be met (MRC, 2000).

Trials remain the preferred research method in much health research and are clearly superior in circumstances where external conditions can be tightly controlled and where the intervention is simple and easily described. However, once we move away from a laboratory setting, or introduce any complexity into the intervention itself, trials are notoriously weak in understanding processes and context (Moore *et al.*, 2014; Connelly and Vanderhoven, 2018; Sandelowski, 2018). Although internally valid, these methods can be both limited and limiting when answering other types of research questions, due to their assumptions about causality and focus on minimising bias (Moore *et al.*, 2014; Moores *et al.*, 2017; Connelly and Vanderhoven, 2018).

Consequently, in studies of complex interventions, such methods focus on controlling variables to reduce bias and increase effectiveness, instead of exploring the effect of context and the agency of the implementers on the experiment (Johnson and Onwuegbuzie, 2004; Moore *et al.*, 2014; Fletcher *et al.*, 2016). They do not accept that bias cannot be completely controlled e.g. from unexpected or challenging contextual variables or the lack of personal objectivity of the researcher (people will always come with experiences and preconceived ideas that influence their decisions) or that context might be embraced and understood to provide more useful explanations (Johnson and Onwuegbuzie, 2004; Moore *et al.*, 2014; Moores *et al.*, 2017; Connelly and Vanderhoven, 2018). This has led to the utility of trials as a methodology for examining complex health interventions being negatively critiqued.

The main criticism is based on the inability of such methods to explain the programme theory (Moore *et al.*, 2014; Fletcher *et al.*, 2016). Programme theory is the Theory of Change (ToC) behind an intervention i.e. the set of assumptions that explain the connections between the activities and the expected outcomes (ActKnowledge, 2013) (see Appendix 11.2.2). Without knowing the programme theory, it is argued, interventions are less likely to succeed (Moore

et al., 2014). The latest MRC guidance on evaluating complex interventions, still in draft form, focuses now on programme theory, as one of its overarching considerations (Craig *et al.*, 2019). One way of representing a programme theory is through the development of a diagram called a logic model which can be used to explain the assumptions underpinning the programme theory (see Chapter 6).

A second major criticism of the trial or experimental method is that it tends to lead to the design of interventions or treatments that are medicalised and can be very clearly described (Coote, Allen and Woodhead, 2004). In such situations, patients/clients are viewed as receivers (subjects), and treatment is given according to a manualised, one-size-fits-all approach, regardless of the needs of individuals (Coote, Allen and Woodhead, 2004; Bryman, 2012; O'Cathain *et al.*, 2013).

It is argued that the dominance of trials, and the possibility of results that indicate unrealistic outcomes, leaves trial results open to raising false hopes about the feasibility and effectiveness of new interventions (O'Cathain *et al.*, 2015; Fletcher *et al.*, 2016). This is especially noticeable when implementing beyond the original setting and/or scaling up and out, where trial conditions cannot be maintained (O'Cathain *et al.*, 2015; Moores *et al.*, 2017). It is suggested this is primarily due to: lack of feasibility testing, lack of knowledge about the necessary environment, the effect of contextual variables and misinterpretation of the mechanisms of impact (Murray *et al.*, 2010; O'Cathain *et al.*, 2015; May, Johnson and Finch, 2016). This is just now being strongly highlighted by Craig et al. (2019).

2.4 Challenge of evaluating complex public health interventions with experimental methodologies

Public health interventions like babyClear© are often complex in their elements and scope, and are placed into open systems, thus challenging the historically experimentalist approach to research and its methods of controlling, randomising and reporting (McCleary *et al.*, 2013). Trial results for complex interventions have been criticised, both by commissioners and providers of health services, for their lack of usability and absence of generalisability when scaling up (Hawe, Shiell and Riley, 2004; Shepherd, 2014; Silverman, 2015; Bryk, 2016; Fletcher *et al.*, 2016). This is of global concern (Awoonor-Williams and Appiah-Denkyira, 2017). It has been suggested that trial conditions, in their remoteness from the real-world where the interventions are implemented, are an impediment to sustaining the outcomes (Hoddinott, Britten and Pill, 2010; Murray *et al.*, 2010; May, Johnson and Finch, 2016; Greenhalgh and Papoutsi, 2018).

Table 2-2: Limitations of trials for evaluation of complex public health interventions

Trial characteristic	**Intervention characteristic**	**Limitation of trial method**
Relies on controlling context	Complex context Controlling impossible	No alternative to laboratory conditions
Relies on reducing bias	Complex intervention Bias inevitable	No alternative method to account for bias
Relies on generalisation	Individual variation Randomisation impossible	Philosophically opposed to variation

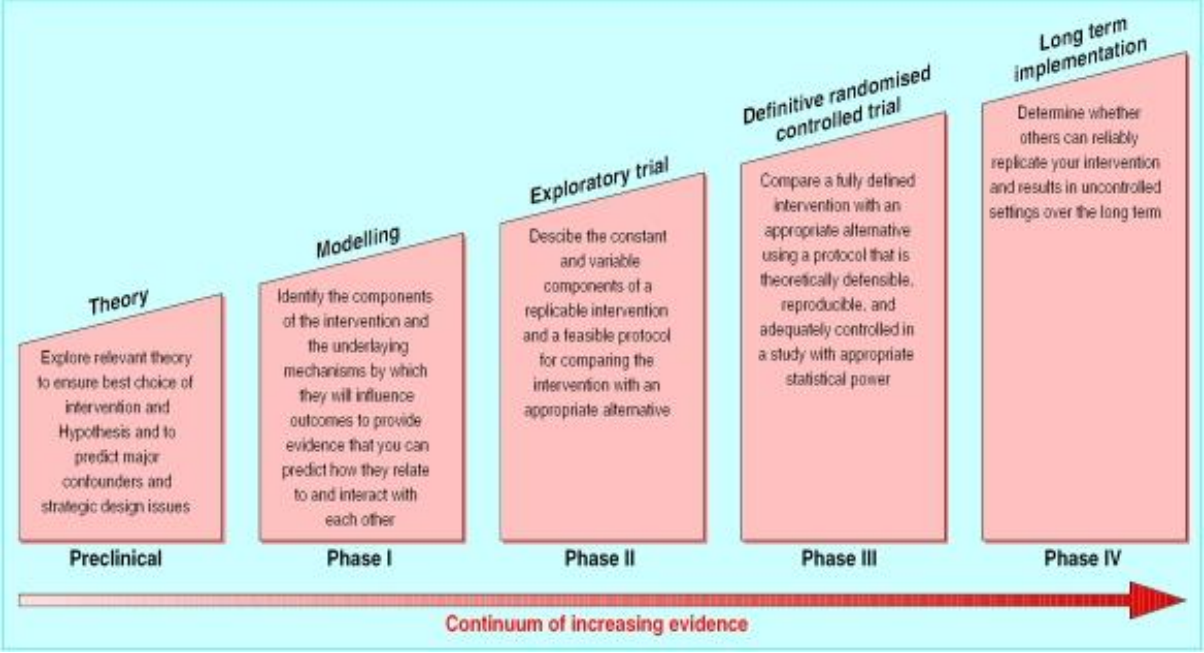
Trial conditions are no longer always viewed as ideal; bias and variation are sometimes embraced to become sources of information to understand the programme theory (Murray *et al.*, 2010; May, Johnson and Finch, 2016; Greenhalgh and Papoutsi, 2018). Methodologies and methods based on alternative philosophies are required to address these limitations of trial methods in evaluating complex, public health interventions (Hawe, Shiell and Riley, 2004; McCleary *et al.*, 2013). This has led to the challenging suggestion that the answer is to open 'the black box' i.e. find out what is happening inside the intervention (Shoveller *et al.*, 2016).

The dangers of this situation - overlooking the process and mechanisms of change and impact - were clearly explained by the authors of the MRC guidance, *A framework for development and evaluation of Randomised Controlled Trials for complex interventions to improve health* (2000). In an article published some years later they said: "**Unless the trials illuminate processes and mechanisms they often fail to provide useful information**. If the result is negative, we are left wondering whether the intervention is inherently ineffective (either because the intervention was inadequately developed or because all similar interventions are ineffective), whether it was inadequately applied or applied in an inappropriate context, or whether the trial used an inappropriate design, comparison groups or outcomes. If there is a positive effect, it can be hard to judge how the results of the trial might be applied to a different context" (Campbell *et al.*, 2007, p455).

Interestingly, the guidance (MRC, 2000) introduced the idea of a "continuum of increasing evidence" (p3) (Figure 2-1). Rather than assuming RCTs were at the pinnacle of a hierarchy, it placed them within an escalating structure; starting with identifying the theory from the known evidence-base, to modelling the ideas, then conducting an exploratory trial before contemplating an RCT, the appropriate outcome measures and indeed the future sustainability of the intervention (MRC, 2000). The idea began to take root that the most

appropriate study design for the purpose, and the stage of discovery, was the one to choose rather than idealising RCTs.

Figure 2-1: Sequential phases of developing randomised controlled trials of complex interventions



(MRC, 2000, p3)

The types of questions that arise in complex interventions, that RCTs struggle to address, began to appear in the guidance (MRC, 2000). The linked concepts of “active ingredients” and “mechanisms of action” were mentioned (MRC, 2000, p2), with acknowledgement that studies needed to use a mixture of research methods to answer the related questions. Beyond effectiveness, these were identified as the questions posed by policy and practice stakeholders, for example about acceptability, fidelity and sustainability (MRC, 2000). Non-experimental (also known as observational) designs were talked about more favourably than previously, accepting that they have a valuable role to play alongside RCTs (MRC, 2000). However, the MRC guidance (2000) was critiqued for its lack of direction in how it should be applied when conducting a study, e.g. how trials should be integrated with other methods and how to consider context (Craig *et al.*, 2008) and there was no mention of knowledge translation.

This conceptual shift continued with further MRC guidance in 2008: *Developing and evaluating complex interventions: new guidance* (Craig *et al.*). It moved away from a drugs trial format to a more flexible, iterative model (Craig *et al.*, 2008). It focused on bringing in

more about context and understanding how an intervention worked (Craig *et al.*, 2008). It created a pragmatic structure which was more sympathetic to mixed methods when evaluating complex interventions, but it still talked in the language of trials e.g. those taking part in the study remained 'subjects' (Craig *et al.*, 2008). In 2009, *Using natural experiments to evaluate population health interventions: guidance for producers and users of evidence* (Craig *et al.*) was published. It aimed to bring together a 'dispersed' literature and improve the use of natural experimental methodology, which it viewed as an underutilised design, with opportunities for study all around us (Craig *et al.*, 2009).

Capturing the interplay between the implementation, intervention and context raises significant challenges for experimental methodology (Moore *et al.*, 2014; Fletcher *et al.*, 2016). Examples include recipients' views and consequent behaviours, reasons behind varying levels of compliance, acceptability of the implementation or the intervention and the fidelity of intervention delivery (Moore *et al.*, 2014). A trial's capacity to absorb meaningful contextual variables and convert them into quantitative terms that accurately reflect reality is limited (Moore *et al.*, 2014). Collecting the relevant information to feed into these types of contextual variables through experimental methods is also difficult; as is controlling them to a level that is acceptable for trial methodology (Zapka *et al.*, 2004; Moore *et al.*, 2014; André and Sjøvold, 2017). Greenhalgh & Papoutsi (2018) argue that it is time for another 'paradigm shift' to address complexity using more adaptable and flexible study designs. Historically the focus has been on efficacy and effectiveness, where trials were seen to be the only 'gold standard', now implementation science with its realist and systems approaches, has gained some credibility and is being promoted not just as an "add-on" but as a "field in its own right" (Craig *et al.*, 2013; Craig *et al.*, 2019, p74).

2.5 Non-experimental methodologies and introduction of the logic model

With the increasing number of complex public health interventions requiring evaluation, researchers had begun to look towards non-experimental methodologies to fill the gap between trials data based on laboratory ideals and real-life implementation (Rogers, 2007). Non-experimental methodologies are subjective and interpretive in nature; they seek the perceptions of participants, construct theory and findings from textual data and embrace contextual confounders (Bryman, 2012). Their main features can be found in Table 2-3.

Table 2-3: Key features of non-experimental designs

Feature	**Benefit**
Subjective, interpretive	Answers non-quantifiable questions, often based on participant opinion or perspective
Bias can be minimised but not excluded altogether	Recognises and accepts that there will always be bias
Based in real-life situations	Reflects what happens in ordinary settings
Emphasis on individual experiences rather than generalisability to populations	Recognises that not everything can be generalised or standardised but where there is difference or common ground learning can be shared
Primarily use qualitative methods e.g. individual and group interviews and focus groups and produce textual data i.e. transcripts, documents	Rich description with depth and meaning derived from lived experiences
Trustworthiness is paramount (credibility, transferability, dependability and confirmability) (Lincoln and Guba, 1985)	Robustness of the data can be confirmed
Rigour through triangulation, peer debriefing, member checking and saturation (DePoy and Gitlin, 2005).	Rigour of the data can be confirmed

(Bryman, 2012, p380-414)

The sort of research questions non-experimental methodologies answer includes:

- Why was the intervention ineffective? Was it the design or was it something to do with the context or the population?
- Why was it effective? What was it about the intervention that meant it worked well? Was it the way the staff presented it or that it had become more acceptable due to a health promotion drive or some other contextual factor?
- Which elements can be transferred to another location and which cannot?

(Bryman, 2012)

The underlying epistemology is one of subjectivity, with an assumption that the truth is complex and filtered through individuals (Bryman, 2012). Ontologically the truth can change

depending on context and circumstance (Bryman, 2012). Non-experimental methodologies are favoured where a) an understanding of the views of participants and how they feel/behave is required and b) the issue of context is pivotal and central to understanding the outcomes (Pawson and Tilley, 1997; Hawe, Shiell and Riley, 2004; Moore *et al.*, 2014). There may be several types and levels of context to consider e.g. political, social, organisational and individual (Blamey and Mackenzie, 2007). Intervention goals are likely to be set at every contextual level, including individual/group behaviour change, organisation and system policy and practice (Blamey and Mackenzie, 2007). A further consideration is that without the explanatory detail behind the statistical outcomes, the results are less open to translation into policy and practice (Shepherd, 2014).

The opportunity to learn how the protocol for the intervention has been delivered and how the process of delivery and implementation links to effectiveness is often missed (O'Cathain *et al.*, 2013; Moore *et al.*, 2014). However, once the process is understood, the potential to develop ways to implement interventions to be more effective, sustainable and transferable is created (May, 2013a; Moore *et al.*, 2014; Schloemer and Schröder-Bäck, 2018). This is the specific contribution of process evaluation. Moore *et* al. (2014, p20) express it in the following series of questions:

1. If an intervention is effective in one context, what additional information does the policy-maker need to be confident that:
    - the intervention as it was actually delivered can be sufficiently well described to allow replication of its core components;
    - another organisation (or set of professionals) will deliver it in the same way;
    - if they do, it will produce the same outcomes in these new contexts?

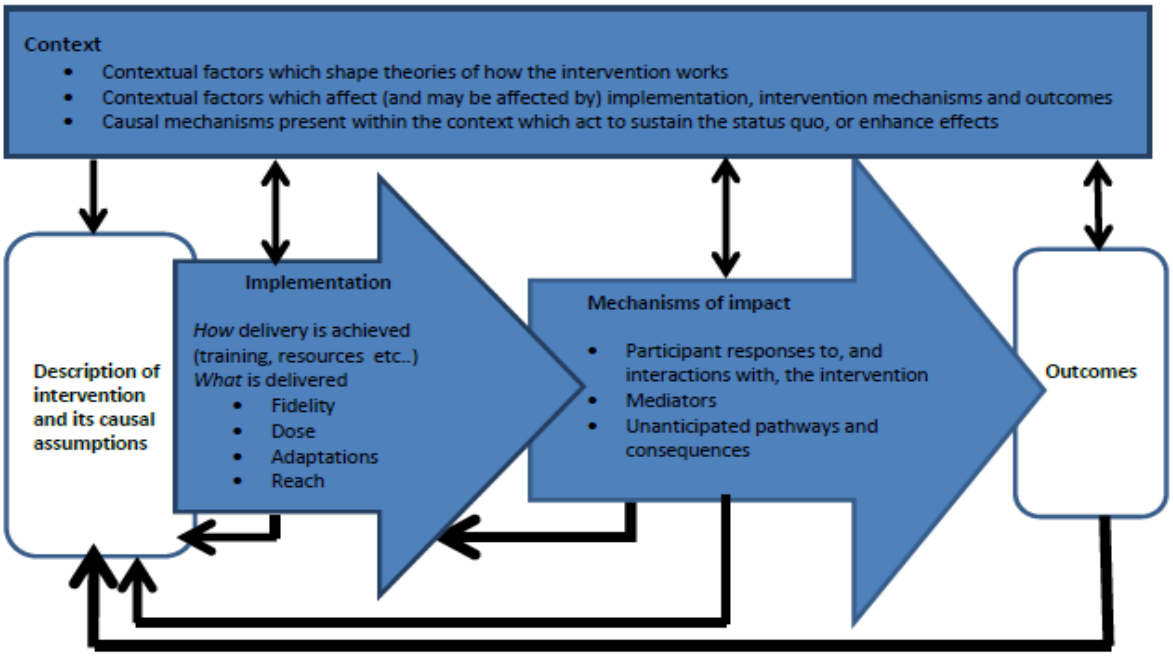
2. If an intervention is ineffective overall in one context, what additional information does the policy-maker need to be confident that:
    - the failure is attributable to the intervention itself, rather than to poor implementation?
    - the intervention does not benefit any of the target population?
    - if it was delivered in a different context it would be equally ineffective?

3. What information do systematic reviewers need to:
    - be confident that they are comparing interventions which were delivered in the same way?

- understand why the same intervention has different effects in different contexts?

In response to this theory-practice dilemma, researchers have been active in systematic reviewing, synthesising of findings, and developing new theories and designs (Moore *et al.*, 2014). MRC guidance on the topic, was published by Moore and colleagues (2014) during the evaluation of babyClear© and provides the underpinning principles for this thesis. It addresses the role of process evaluation in evaluating complex interventions (Moore *et al.*, 2014). It incorporated the latest theoretical and methodological thinking at the time of thesis writing and postulates a new framework for linking process evaluation functions; including using primary, qualitative studies as a crucial part of an overall, experimental design (Moore *et al.*, 2014). It has been used within this thesis as a framework to understand a) what helps and hinders implementation at scale, and b) how interventions can be tailored to context without losing effectiveness. However, complementary guidance on evaluating complex interventions is in the process of being updated (Craig *et al.*, 2019). The key functions and interactions of a process evaluation, as presented in Moore et al. (2014), are displayed in Figure 2-2.

Figure 2-2: Key functions of process evaluation and relationships amongst them



(Moore *et al.*, 2014, p11)

Blue boxes represent components of process evaluation, which are informed by the causal assumptions of the intervention and inform the interpretation of outcomes.

Within the model there are three main elements, termed functions: 1) context, 2) implementation and 3) mechanisms of impact. These three functions are sandwiched between the preparation or pre-implementation stage and the final outcomes (Moore *et al.*, 2014).

2.5.1 The logic model

Moore *et al.* (2014) identify logic modelling as a significant element of the pre-implementation stage i.e. within description of the intervention and its causal assumptions. They define a logic model as "a diagrammatic representation of an intervention"; it is usually drawn up prior to implementation and describes how it is anticipated the intervention will work (Moore *et al.*, 2014, p8). This view is strongly supported by Craig *et al*. (2019). The logic diagram has four essential parts:

- delivery mechanisms (e.g. how resources will be applied to ensure implementation)
- intervention components (what is to be implemented)
- mechanisms of impact (the mechanisms through which an intervention will work)
- intended outcomes.

(Moore *et al.*, 2014, p8)

Logic modelling is a tool that articulates the ToC in a diagrammatic manner (W.K. Kellogg Foundation, 2004) (Appendix 11.2.2). It was initiated by the W. K. Kellogg Foundation (2004), to equip the project managers who received grants from their charitable foundation, to maximise project effectiveness. It offers a way to think through a series of complex relationships and set them out in a visual manner and helps to: "facilitate thinking, planning, and communications about program objectives and actual accomplishments" (W.K. Kellogg Foundation, 2004). It has gained ground as a useful project management tool (Papoutsi *et al.*, 2016) and is recommended by Moore *et al.* (2014) to focus study research questions and tabulate the processes within the intervention and implementation.

Simple logic models include boxes/columns for three programme elements; i) inputs e.g. processes, resources/activities, ii) outputs and iii) outcomes, including impact (W.K. Kellogg Foundation, 2004). They are recommended for clarifying and mapping out the evidence base for the intervention formatively using a series of sources, including standard academic tools such as expert knowledge and literature reviewing (Moore *et al.*, 2014). They also recognise the role of experience and 'common sense' (Moore *et al.*, 2014); a view supported by Michie & Prestwich (2010) when discussing behaviour change interventions, who contend

that they are sometimes developed pragmatically rather than deduced from theory. If a pragmatic, formative evaluation process is used, then the researchers need to go to the programme developers and work out the causal assumptions with them (Evans, Scourfield and Murphy, 2015).

Evidence-based or pragmatic, the underlying ToC is one element that requires recognition, if the mechanisms of impact and active ingredients by which an intervention is effective are to be understood (Pawson and Tilley, 2004; Michie and Prestwich, 2010; Wight *et al.*, 2015; Breuer *et al.*, 2016). This knowledge is critical in scaling up or transferring an intervention (Pawson and Tilley, 2004; W.K. Kellogg Foundation, 2004; Michie and Prestwich, 2010; Craig *et al.*, 2019). Use of logic modelling is gaining ground and has been found to be particularly successful when working in a complex environment (Lamont *et al.*, 2016). For example, McGowan *et al*. (2010), in developing a service for pregnant smokers, started by drawing a logic model. Chamberlain *et al*. (2013) in their Cochrane review: *Psychosocial interventions for supporting women to stop smoking in pregnancy* created a logic model to represent the factors they expected to be assessing in their complex review. However, they can be open to misuse as, "little more than strings of variables" in trial situations unless their purpose is fully understood and embraced (Bonell *et al.*, 2018, p10 of 12).

2.5.2 Context

MRC guidance also reflects how the issue of context has come to the fore (Moore *et al.*, 2014; Craig *et al.*, 2019). Draft guidance says: "taking context into account throughout is crucial" (p26) to evaluating complex interventions (Craig *et al.*, 2019). Context refers to: "factors external to the intervention which may influence its implementation, or whether its mechanisms of impact act as intended" (Moore *et al.*, 2014, p8). Coldwell (2019) is in sympathy with this view, showing that some logic models are designed to alert the researcher to the importance of context; however, he also points out how the complexities are often not systematically examined and still missed.

2.5.3 Implementation

The two main aspects of implementation are: 'How delivery is achieved' and 'What is achieved' (Figure 2-2). There are also active ingredients and mechanisms of action to consider (Moore *et al.*, 2014). That is: **"intervention components that can be specifically linked to effects on outcomes, such that, were they omitted, the intervention would be ineffective"** and **"the underlying reasons why the active ingredients have their particular effects"** (McCleary *et al.*, 2013, p1 of 9). Mechanisms answer the question how?

i.e. how is the process affected by context and relates to the degree to which a standard intervention requires adaptation to realise the anticipated outcomes (Moore *et al.*, 2014; Escoffery *et al.*, 2018). 'Dose' and 'reach' answer the question what? i.e. they are principally quantitative measures (Moore *et al.*, 2014), so not the focus of this thesis. Fidelity and adaptation, the two other aspects, however, are qualitative issues of specific interest and will be explored (Moore *et al.*, 2014).

Understanding the process of implementation can counter-balance trial designs with a more personalised view of practice (Coote, Allen and Woodhead, 2004; O'Cathain *et al.*, 2013; Fletcher *et al.*, 2016). Non-experimental methodologies can be used in situations which do not lend themselves to controlling or standardisation (Greenhalgh *et al.*, 2004; Hawe, Shiell and Riley, 2004; Craig *et al.*, 2008; Craig *et al.*, 2009; Moore *et al.*, 2014; Connelly and Vanderhoven, 2018). For example, where it would be unethical to control for variables, the context does not allow for controlling and/or there is an expectation that people are not passive recipients of interventions, treatments or services but instead are active actors and make a variety of choices (Bryman, 2012). These designs can capture the relevant data about individual or group choices (Bryman, 2012; Shepherd, 2014). This is important because these choices affect outcomes (Bryman, 2012). Examples of the types of suitable studies include evaluation of social programmes characterised by partnership approaches in communities, third sector and government backed services, working across disciplines and with a focus on trying to solve intractable problems in society e.g. Promoting Alternative Thinking Strategies (Education Endowment Fund, 2015), Lyndon Project (Connelly and Vanderhoven, 2018).

Process evaluation is becoming more acceptable as an adjunct to effectiveness and cost-effectiveness studies, as a way of understanding how an intervention protocol must adapt and change to deliver the outcomes (Moore *et al.*, 2014; Craig *et al.*, 2019). Process evaluation methods use non-experimental methodologies and have several benefits (Moore *et al.*, 2014). O'Cathain and Moore, two of the authors of the MRC guidance (2014), writing with colleagues for the British Medical Journal, set out two tables: one of process evaluation's value in generating evidence of effectiveness and another of how it can focus the research questions (O'Cathain *et al.*, 2013). These are two highly accessible tools when thinking about how to optimise the use of process evaluation. Another issue they highlighted was the benefit of using process evaluation at the pre-trial stage "to reduce the chance of finding unwelcome surprises during the main trial" (O'Cathain *et al.*, 2013, p13). They have written guidance on using qualitative methods as part of a feasibility study prior to a trial, either alone or integrated with quantitative methods (O'Cathain *et al.*, 2015). Again, this

offers a useful, step-by-step tool to think through the application of process evaluation (O'Cathain *et al.*, 2015).

Nevertheless, qualitative approaches are also not without bias but make a different set of assumptions to experimental designs. They accept high degrees of relativity and non-standardisation (Johnson and Onwuegbuzie, 2004). They accept that researchers are inevitably biased and use tools such as reflection and transparency to deal with this challenge (Schön, 1987; Gibbs, 1988). Rather than prioritising generalisability they focus on trustworthiness and use alternative methods to ensure rigour e.g. triangulation, peer debriefing, member checking and saturation (DePoy and Gitlin, 2005). Being rooted in relativism and interpretivism - and having developed alternative ways to deal with bias - makes qualitative methodologies suitable to answer research questions about context, complexity and agency (Bryman, 2012).

2.6 Exploring the theory-practice gap

Realisation has thus been growing that, although trial designs have their strengths, they are not the strongest design for all and every type of study at every point in the journey of discovering evidence (MRC, 2000; Sandelowski, 2000; Moore *et al.*, 2014; André and Sjøvold, 2017; Connelly and Vanderhoven, 2018; Craig *et al.*, 2019). Instead of choosing the study design based on the methodology, it needs to be chosen to answer the research question and provide the required knowledge (Bryman, 2012; Sandelowski, 2018). Research around SiP is a good example of the way methodologies have been developing: once it was established by trial methodology that smoking was associated with multiple adverse health outcomes for the mother and growing baby (Doll *et al.*, 1994; RCP & TAG, 2010), the next question became: what can we do about it?

The fact that experimental or trial methodologies (positivist in nature) have been preferred historically, over other methodologies, is a barrier to understanding this gap between the experimental evidence and the outcome and translating this knowledge into policy and practice (Coote, Allen and Woodhead, 2004; O'Cathain *et al.*, 2013). Coote, Allen and Woodhead (2004) said: "investment in health-related research remains **dramatically skewed towards treatment and cure**. Too little has been invested in exploring how change occurs at all levels, and in how the expertise of practitioners and residents can be recognised and shared more widely" (p50) (emphasis added). Ten years later, Evans, Scourfield and Murphy (2015) were arguing that pragmatic, formative process evaluations still need to 'carve out' their space more fully.

It is becoming more acceptable to argue that it is equally important to understand not just, does the intervention work, but also, for who, and in what circumstances (Pawson and Tilley, 1997; Rogers, 2007; Shepherd, 2014; Bonell *et al.*, 2018; Craig *et al.*, 2019). This in turn has led to the development of methodologies that identify how an intervention works, and the mechanisms of impact and active ingredients that bring about (or fail to bring about) the expected effect (Pawson and Tilley, 1997; Rogers, 2007; Kreindler, 2018; Brand *et al.*, 2019). Realist evaluation is one such approach that is being used to explain the process of implementation (Pawson and Tilley, 1997; Pawson and Tilley, 2004). Originally, the authors stated the aim of realist evaluation as: "… the development, testing and refinement of programme theory" (Pawson and Tilley, 2004, p13). They set out the methods to identify the programme theory using context, mechanism, outcome configurations (Pawson and Tilley, 2004). These tentative theories are initially derived from a variety of sources, including documents, evaluation and other relevant literature, practitioners, programme architects and experts in the field (Pawson and Tilley, 2004). These are then tested using methods designed for the purpose; the data are then analysed to compare the real and hypothesised outcomes (Pawson and Tilley, 2004). The researchers have deliberately sought to counter their own arguments as a way of increasing rigour in developing their approach (Greenhalgh *et al.*, 2009).

Realist evaluation is like NPT in that it is an interpretative and iterative method where conditional causality is elicited i.e. understanding the circumstances required for an effect to be achieved (Pawson and Tilley, 2004; May *et al.*, 2007b; Greenhalgh *et al.*, 2009). The applications envisaged for it include "prospectively at delivery, trying to figure out the best way to marshal together a programme or service. It can be placed concurrently with a programme, asking the traditional question about whether and in what respects it is working. It can be put in place retrospectively, calling on all past evidence about former incarnations of an interventions (sic) in order to inform whether and what guise it might be targeted at an impending problem" (Pawson and Tilley, 2004, p13). Again, like NPT, it is recommended for use at a number of points in the process evaluation cycle (Moore *et al.*, 2014). However, realist evaluation is epistemologically at odds with trial designs, believing as it does, in the significant influence of context and the cumulative and iterative nature of knowledge building, so it tends not to be used within or alongside trials (Blamey and Mackenzie, 2007; Rycroft-Malone *et al.*, 2016). In this it differs from NPT, which, it could be argued, is more able to co-exist with trial designs, as discussed in Chapter 9.

NPT, the mid-range theory under scrutiny, was used within a process evaluation to look at the implementation process (May and Finch, 2009). Although there is an increasing focus on

methodologies that investigate why an intervention is (in)effective and in which context/circumstances it is (in)effective (Moore *et al.*, 2014; André and Sjøvold, 2017; Craig *et al.*, 2019), one of the criticisms of interpretivist approaches is that they are uncontrolled and variable and therefore the findings are unreliable (Shepherd, 2014). Reporting guidelines, such as COnsolidated criteria for REporting Qualitative research (COREQ) (Tong, Sainsbury and Craig, 2007), now exist for qualitative research. They aim to raise and maintain quality and transparency when reporting on methods (Tong, Sainsbury and Craig, 2007). Even here though, there is a tendency to judge with a positivist mindset, using generic checklists (Tong, Sainsbury and Craig, 2007; Wight *et al.*, 2015). It is important that methods are clarified so the study can be independently examined, although exactly repeating the steps like an experiment is neither possible nor desirable (Tong, Sainsbury and Craig, 2007; O'Cathain *et al.*, 2015). Using COREQ, or similar, is important as is finding new, alternative ways to promote transparency, that are sympathetic to interpretivist approaches (O'Cathain *et al.*, 2015).

2.7 Mixed method studies

A mixed method was used in the original evaluation in this study's example. Contrary to common understanding about the hierarchy of research methods, which places experimental methods at the pinnacle, combining experimental and non-experimental methods has been shown to increase replicability and generalisability, not in the laboratory, but in real services (Johnson and Onwuegbuzie, 2004; Moore *et al.*, 2015). Trials are becoming more readily recognised as one method among others in certain types of research (Moore *et al.*, 2014; Shepherd, 2014; Raine *et al.*, 2016). Concessions are now beginning to be made and the design of choice may also look towards complementary approaches (Moore *et al.*, 2014). The non-experimental element in the study example lent itself to identifying the "steps of change" and "key functions" that Hawe Shiell and Riley (2004, p1562) suggest need to be discovered to allow for fidelity and adaptation to be satisfied.

The case has just been made for putting more value than has been customary on qualitative methodologies to answer certain types of research question. However, even qualitative methods can struggle to fully comprehend the underlying processes of implementation (Pawson, 2006; May, Johnson and Finch, 2016; Connelly and Vanderhoven, 2018). The corollary to this is not to undervalue quantitative methodologies but instead consider their complementary use within process evaluation (Brannen, 2005; Moore *et al.*, 2014; Connelly and Vanderhoven, 2018). Mixed method study designs are used to bring both aspects together (Bryman, 2012). Still, when using quantitative and qualitative methods together,

there often remains a lack of integration between the two methods within the evaluation (Moore *et al.*, 2014; Vogl, 2018). Creating a smooth flow of quantitative results and qualitative findings, feeding into one another and building up a picture that answers the research questions, often remains elusive and requires specifically designed methods (Wenger-Trayner *et al.*, 2017; Vogl, 2018).

The importance of developing methodologies that explore the theory-practice gap has become widely recognised (Moore *et al.*, 2014; Craig *et al.*, 2019). What Works Network was set up by the UK government in 2013 to "improve the way government and other organisations create, share and use (or 'generate, transmit and adopt') high quality evidence for decision-making" (Cabinet Office, 2019). It recommends that the trials-based Cochrane Collaboration and NIHR work more closely with NICE to address methodological shortcomings (Shepherd, 2014). The Cochrane Collaboration and Joanna Briggs Institute (JBI) have also made an agreement to work more closely together (Cochrane, 2016). The JBI is another international organisation that systematically and rigorously reviews health literature, but its roots are in nursing and it comes from a more inclusive standpoint, incorporating and equally valuing both qualitative and quantitative methods (JBI, 2018). These moves are signs of this increasing understanding of the importance of complementarity between qualitative and quantitative methodologies; that in some circumstances the two parts mutually complete each other, rather than their traditional standpoints of competition or undervaluing of the other (Hawe, Shiell and Riley, 2004; Johnson and Onwuegbuzie, 2004; Zapka *et al.*, 2004; O'Cathain *et al.*, 2013; Moore *et al.*, 2014; O'Cathain *et al.*, 2015).

How to do this is a topic for further research and work is ongoing to develop more satisfactory methods (Bonell *et al.*, 2018; Connelly and Vanderhoven, 2018; Vogl, 2018). For example: tools developed by O'Cathain *et al.* demonstrate clearly how process evaluation and RCTs can work together when looking at complex interventions (O'Cathain *et al.*, 2013; O'Cathain *et al.*, 2015). These methods may benefit from using a theory like NPT to understand the process (McIntyre *et al.*, 2018). However, the place of mixed method designs continues to be debated (Marchal *et al.*, 2012; Bonell *et al.*, 2013; Marchal *et al.*, 2013; O'Cathain *et al.*, 2015; Sandelowski, 2018). Bonell *et al*. (2018) argue that the antagonism between trialists and social scientists acts as a barrier to improving trial methods of social interventions (O'Cathain *et al.*, 2013; O'Cathain *et al.*, 2015). Not all researchers - in principle - agree with mixed methods; some arguing that it is a fruitless search as trials and realist approaches are incompatible (Marchal *et al*., 2013). Full integration during data

collection and analysis raises methodological issues and researchers disagree over satisfactory resolutions (O'Cathain *et al.*, 2015; Vogl, 2018).

The continuing challenge in the evaluation of complex interventions is understanding how to make allowance for context and complexity within interventions and systems and still produce the desired outcomes (Moore *et al.*, 2014; Craig *et al.*, 2019). As reflected above, research and evaluation have been moving towards using multiple methodologies to answer implementation and sustainability-based research questions to understand and support successful outcomes (Craig *et al.*, 2008; Craig *et al.*, 2009; Moore *et al.*, 2014). Operationalising how to reach this understanding has created a move towards using alternative methods (Moore *et al.*, 2014). Evaluating the implementation of babyClear© is an example of using a natural experiment for research. In natural experiments controlling is by circumstance rather than design i.e. "events, interventions or policies which are not under the control of researchers, but which are amenable to research which uses the variation in exposure that they generate to analyse their impact" (Craig *et al.*, 2009, p4). They sit within the broad field of experimental methodology but recognise that full randomisation and controlling is not always possible (Craig *et al.*, 2009).

In this thesis I argue that there is a need to develop the means to evaluate the implementation of complex, public health interventions more successfully i.e. with minimum loss and maximum gain for all stakeholders (e.g. Raine *et al.*, 2016; Moores *et al.*, 2017). I contend that a shift is required to understand the theory-practice gap by moderating the dominance of the positivist paradigm in favour of valuing subjective, interpretivist ontologies as equal but different; so that both methodologies can be used complementarily rather than competitively (O'Cathain *et al.*, 2013; Moore *et al.*, 2014; Raine *et al.*, 2016). It has been argued that this is likely to increase effectiveness, as it has the potential to answer both process and outcome research questions more comprehensively (Moore *et al.*, 2014; Craig *et al.*, 2019). This has resulted in recent years in the progressive development of complexity theories and evaluation methods that respond to the changing demands of the health implementation field, exemplified in the growth of implementation science (Greenhalgh *et al.*, 2004; Walton, 2016; Lynch *et al.*, 2018). A reflection of this development is the success of BMC Implementation Science, which is aiming to fill this void (BMC Implementation Science, 2019). The next step is to translate this knowledge, based on understanding both the evidence and the theory-practice gap, into normalising interventions more smoothly.

2.8 Conclusion

The academic research environment outlined above has influenced the data for this study, in that the intervention was based on trials evidence that had been incorporated into NICE PH Guidance (2010), but the causal assumptions for action and change were deduced pragmatically. Within the evaluation, the effectiveness study initially drove the plan for data collection. The design did not allow for inter-weaving of data, where one informed the other, or for the two methodologies to be fully complementary or well-integrated.

The present academic research environment can be summarised under the following headings:

Previous dominance of experimental methodologies in health research
Continuing challenges to the value of qualitative methodologies
Call for a balanced methodological approach.

Dominance of experimental methodologies

It was argued that the dominance of trials and a positivist worldview, and the tendency towards unrealistic expectations for outcomes, leaves results open to raising false hopes about the feasibility and effectiveness of new interventions. This was especially noticeable when implementing elsewhere and/or scaling up and out. It was noted that trials were weak in understanding processes; however, it was suggested, understanding the process of implementation using qualitative methods could counter-balance this with a more personalised view of practice. Qualitative approaches make a different set of assumptions. Being rooted in relativism and interpretivism, and having developed alternative ways to deal with bias, they are suitable to answer research questions about context, complexity and agency.

Continuing challenges to the value of qualitative methodologies

The review of the literature on implementing complex interventions supports three key arguments: the value of interpretivist ontologies, the underprivileged status of qualitative research and the importance of knowledge translation. There is a growing demand for these to be addressed.

Call for a balanced methodological approach

Implementing complex public health interventions often requires a mixed method approach, bringing together the strengths of both positivist and interpretivist study designs. Methods to accomplish this successfully are being debated and developed.

In conclusion, the predominant, positivist assumptions of the research environment need to be questioned and new theoretical frameworks and methodologies developed to strengthen the use of knowledge gained through non-experimental research. Process evaluation, an example of this, requires an approach that is complementary and integrates easily with experimental methodologies.

2.9 Chapter summary

This chapter has described the history, development and current debate over the evaluation of the implementation of complex interventions and reflects on the shift in perception towards including interpretive approaches. It has commented on the role of process evaluation methodology, most notably in MRC guidance, and has introduced logic modelling. Examples were given of recent moves to address the issues and identify ways to strengthen designs and explore the theory-practice gap. More background to methodologies and methods can be found in Appendix 11.2.2.

Chapter 3 NORMALISATION PROCESS THEORY

3.1 Introduction

Chapter 3 gives an outline of NPT; the theory being examined in this thesis. NPT was developed in response to evidence of a theory-practice gap and assumes that it is insufficient to know that something 'works' or is effective. Such findings are often less than helpful for practitioners in implementing change at scale or in different settings. It thus aims to bridge an important knowledge translation gap and assist in understanding the process involved when introducing an intervention. NPT focuses on the specific activities required for moving an experimental procedure or practice into habitual use, i.e. for normalisation. It can be used in several ways i.e. as the theoretical framework, to sensitise the researcher to the issues, or to analyse the data; and also at different time points in the investigative cycle. An introduction is given to the important effect of environment and specific contexts on the implementation process, and the attributes of NPT, found in the literature.

This chapter draws on the literature in two topic areas: the development of NPT and the environments in which NPT has been used. Then it gives a critique of its use so far. It provides a basic understanding of the theory and how it relates to the underlying issues with which this thesis contends, including identifying the normalisation process and the effect of organisational culture and context on normalisation. Justification for choosing NPT is explored through identifying the various ways it can be applied, a rationale which is consistent with many other studies (May *et al.*, 2018). The development of thinking around complex interventions has been covered in Chapter 2.

3.2 Origins of NPT

NPT is a theory that is interested in understanding the process of introducing an innovation by creating research knowledge using a realist approach, then seeking to use the new knowledge to ensure normalisation at the frontline and maximise the efficacy and effectiveness of the implementation (Mair *et al.*, 2008; May and Finch, 2009). NPT is an innovative, evidence-based, mid-range theory i.e. it is not abstract, but ready to be directly applied by individuals (Boudon, 1991; May and Finch, 2009). It has been developed over the last decade alongside the debate about how to answer concerns regarding understanding how to implement complex interventions to maximise their potential (May *et al.*, 2007b; May and Finch, 2009; May, Johnson and Finch, 2016; May *et al.*, 2018; Craig *et al.*, 2019).

The origins of NPT lie in the observation by a group of researchers that the favourable experimental evidence relating to use of e-health technologies did not translate successfully

when put into wider practice (May, 2006). It was becoming apparent that there was a need for a different theoretical framework to explain the process of implementation of complex interventions like these (Craig *et al.*, 2008). Those working in the field were responding to the oft-noted gap between theory and evidence on the one side, compared with implementation and practice on the other (May, 2006).

The developers of NPT aimed to equip clinicians and researchers to improve interventions and their implementation by understanding the processes and identifying the requirements for normalisation (May, 2006; May *et al.*, 2007a; Finch *et al.*, 2012). Normalisation is the central tenet of Normalisation Process Theory (NPT) (May *et al.*, 2007b; May and Finch, 2009). Normalisation is defined as: **"the embedding of a technique, technology or organisational change as a routine and taken-for-granted element of clinical practice"** (May, 2006, p2 of 11). This idea of normalisation, conceptualised within NPT, has been recommended as a qualitative framework for the process element when studying complex public health interventions (May and Finch, 2009; Moore *et al.*, 2014). The contemporary dilemma, in terms of the theory-practice gap, is explored further in Chapter 2.

3.3 Development of Normalisation Process Model

NPT was pre-dated by the development of the Normalisation Process Model (NPM), which is a social, interpretive, prospective model (May *et al.*, 2007b). NPM was built through re-analysis of existing qualitative studies which looked from a sociological standpoint for methods of successful innovation (May, 2006). Analytical propositions based on the identified methods were then created and systematically tested to confirm the constructs (May, 2006). Carl May began to publish on NPM in 2006 and subsequently has expanded his team and disseminated the process of theoretical development into NPT (McEvoy *et al.*, 2014; May *et al.*, 2018) (see Table 3-1). The theory continues to be tested and refined and is moving towards a more general theory of implementation (May, Johnson and Finch, 2016; Lynch *et al.*, 2018; May *et al.*, 2018). When applying NPM/NPT, they are looking at the implementation of interventions *in situ* rather than under trial conditions, recognising from the start the importance of context and holism (May *et al.*, 2003; May *et al.*, 2007b; Elwyn *et al.*, 2008; May, Johnson and Finch, 2016).

Table 3-1: Key papers reporting the development of NPT

Theoretical focus	**Theoretical content**	**Research questions**	**Empirical focus**
2006 – Users' interactions with objects in implementation processes	Analysis of mechanisms of collective action (May *et al.*, 2007a; May and Finch, 2009)	What factors promote or inhibit the routine incorporation of complex interventions in practice? How do they affect implementation processes and outcomes?	How complex interventions are operationalised by their users
2009 – Agency within implementation processes	Analysis of mechanisms of agents' contributions to implementation processes (May and Finch, 2009; May, 2013b)	What factors promote or inhibit the implementation, embedding and integration of practices? How do they affect implementation processes and outcomes?	The work people do when they implement a new technique, technology or organisational intervention
2013 – Resource mobilisation in implementation processes	Analysis of social structural resources and social cognitive resources available to agents as they invest in implementation (May *et al.*, 2007b; May, 2013a)	What factors promote or inhibit the mobilisation of structural and cognitive resources for implementation? How do they affect implementation processes and outcomes?	How implementation processes work over time
2013 – Implementation as adaptive self-organising in complex systems	Analysis of properties of interventions as events in systems and adaptive responses to emergence (May, Johnson and Finch, 2016)	What factors promote or inhibit the adaptation and self-organisation in complex systems? How do they affect implementation processes and outcomes?	How implementation processes differ between settings

(May, Johnson and Finch, 2016)

In his early paper May (2006) described the outline of the NPM. As a conceptual model NPM was designed to bring understanding of processes and social contexts that were conducive to workability and integration and make them explicit (May, 2006; May *et al.*, 2007b). It had four elements (see Table 3-2) and its focus was the way complex interventions were operationalised by their users (May, Johnson and Finch, 2016).

Table 3-2: Core constructs of NPM

Core construct	**Interactional workability**	**Relational integration**	**Skill-set workability**	**Contextual integration**
Definition of core construct	How the work is enacted by the people doing it	How the work is understood within the networks of people around it	The place of work in a division of labour	The organisational sponsorship and control of work
Dimension 1 of core construct	Congruence – affect on co-operative interaction over work	Accountability – affect on the knowledge required by its users	Allocation – affect on the ways that work is defined and distributed	Execution - affect on the mechanisms that link work to existing structures and procedures
Dimension 2 of core construct	Disposal – the normal patterns of outcomes of the work	Confidence – affect on the ways that the users understand the actions of people around them	Performance - affect on the ways in which the work is undertaken and evaluated	Realisation – affect on the mechanisms for allocating and organising resources

(Adapted from May *et al.*, 2007b) (Original spelling used)

Early uses of the NPM focused on two areas: e-health and application of clinical guidelines (e.g. Finch, Mair and May, 2007; Finch, 2008; Gask *et al.*, 2008; Morriss, 2008; Kennedy, 2010). The originators have pursued a deliberate policy of sharing, first the NPM then the NPT, encouraging broad usage and dialogue between researchers, modifying it and collaborating with other teams to apply NPM/NPT in a variety of contexts (May *et al.*, 2007a;

May *et al.*, 2007b; Mair *et al.*, 2008; Murray, May and Mair, 2010; Bouamrane, Osbourne and Mair, 2011; MacFarlane and O'Reilly-de Brún, 2012; Mair *et al.*, 2012).

It became clear that the focus on collective action in the NPM needed to be expanded; that there was a requirement to address the situation before and after operationalisation i.e. preparation and appraisal (McEvoy *et al.*, 2014). An outline for NPT was published in 2009 (May and Finch) which set out a theory to help understand how to make complex practices workable and integrate them into existing systems in ways that took context into account. Hence the interest in using NPT in the evaluation of babyClear©.

3.4 Development of NPT

NPT, and previously NPM, were built out of pre-existing sociological and psychological theories, which automatically introduced multiple variables through 'wider contexts of multiple sources of contingency and a wide variety of confounding factors' (May, 2006; May *et al.*, 2009; May, 2013b). This was in contradiction of the widely held views concerning experimental approaches as the preferred option for study designs (Craig *et al.*, 2009). Instead the developers drew on alternative sources that looked more towards the humanities than the physical sciences for inspiration (Gask *et al.*, 2010). For example, a key theory, Diffusion Theory, was a sociological theory attributed to Rogers (1962), a rural sociologist, who noted the way that a new agricultural idea was taken up and spread to other farmers. With further work Valente and Rogers (1995) developed a broader theory, based on the rate of uptake of a new idea among a group, and identified the core element as an individual's or organisation's propensity for innovation. This was used by Greenhalgh *et al*. (2004) in an extensive and much-cited "systematic review of the literature on the diffusion, spread and sustainability of innovations in the organisation and delivery of health services" (p1).

Fundamental to NPT, is the notion that it is complexity that is at the root of many of the barriers to normalisation (May, 2006). This appears to reflect Dooley (1997)'s thinking about the interactional nature of systems, be they natural or artificial, and the impact that they have on one another. May (2006) went on to cite Greenhalgh *et al*. (2004)'s recommendation of a whole systems approach in healthcare and their work encouraged May to bring in theories such as Actor-Network Theory (Latour, 2005), Complex Adaptive Systems Theory (Dooley, 1997) and Structuration Theory (Giddens, 1984), referred to in his early paper (2006). These organisational theories became foundational to NPT, along with its sociological frame of reference and its desire to include a macro/systems-level context (May, 2006). The influence of Actor-Network Theory (Latour, 2005) can be seen in NPT where people are seen as part

of a network or system i.e. its context, that impacts on the individual's or the organisation's ability to normalise an intervention.

There are other groups of theories that are more concerned with the micro/individual level of action e.g. educational and cognitive psychology theories of change (Straus, 2009). May (2006) identifies papers based on psycho-social, behavioural theories, such as those published by Michie and colleagues in this group (Michie *et al.*, 2005; Michie, van Stralen and West, 2011; Michie *et al.*, 2013). These micro level theories are reflected in the core concepts, especially coherence and cognitive participation (May and Finch, 2009).

Giddens (1984) was keen to integrate these two underpinnings concepts of sociological thought, structure/organisation and individual agency, without giving either supremacy, postulating that social systems and activities are created through being mutually enacted. This idea from Giddens (1984) is encapsulated in the thinking around the first core construct that emerged, collective action, and from which May (2006) lifts the terms 'routinisation' and 'reflexive monitoring', one of NPT's later core concepts (May and Finch, 2009).

While drawing upon all these theories, May criticises them for focusing either at a macro or a micro level; although he acknowledges that they made a significant contribution to explaining systems and implementation processes, he maintained that they still struggled to work with complexity and context (2006). May was always interested in the factors that promote or prohibit certain activities *en route* to normalisation (see Table 3-3).

Table 3-3: Summary statement of NPT

Theoretical proposals	**Explanatory statement**
a) Material practices become routinely embedded in social contexts as the result of people working, individually and collectively, to implement them.	Implementation processes are therefore organised and organising expressions of human agency that involve patterns of dynamic and contingent interactions within a specific context, over time.
b) The work of implementation is operationalised through four generative mechanisms (*coherence*; c*ognitive participation*; *collective action*; *reflexive monitoring*).	These are affected by factors that promote or inhibit the routine embedding, or normalisation, of a practice in its social contexts – the immediate and organising components outlined in Table 3-4. The embedding of a practice is thus dependent on organised and organising agency.
c) The production and reproduction of a material practice requires continuous	This continued investment sustains the integration of a practice in its social contexts.

investment by agents in ensembles of action that carry forward in time and space.	

(May and Finch, 2009, p540)

In a radical move, May wanted NPT to operate at both levels simultaneously, so he created a mid-range theory, that 'sits beneath these higher level perspectives (e.g. Actor Network Theory) and focuses on the specific sets of activities that are involved in enacting and embedding ensembles of practice' (May, 2006; 2013a, p26). Key terms were defined in their 2009 paper (see Table 3-4).

Table 3-4: Definitions of NPT terms

Term	**Definition**
Work	"purposive social action that involves the investment of personal and group resources to achieve goals"
Practice	"the things that people do to perform certain acts and meet specific goals"
Implementation	"the material practices that are produced, reproduced, and transformed, in relatively formal settings – within an institutional or organisational framework – which are consciously composed and purposively directed"
Normalisation	"the work that actors do as they engage with some ensemble of activities … and by which means it becomes routinely embedded in the matrices of already existing, socially patterned, knowledge and practices"

(Adapted from May and Finch, 2009, p539-540)

In this paper three new theoretical core concepts, also known as generative mechanisms - coherence, cognitive participation and reflexive monitoring - were identified as key factors in the successful 'normalisation' of a new practice (May and Finch, 2009; Finch *et al.*, 2012; Mair *et al.*, 2012) (see Table 3-5). Table 3-5 includes the individual investment that actors, such as HCPs, make to normalise an intervention, in terms of these concepts.

Table 3-5: NPT mechanisms, components and investments

Components	**Mechanisms**			
	Coherence	**Cognitive participation**	**Collective action**	**Reflexive monitoring**
Components (1) Immediate work	Differentiation Individual specification	Initiation Legitimation	Interactional workability Relational integration	Systematisation Individual appraisal
Components (2) Organising work	Communal specification Internalisation	Enrolment Activation	Contextual integration Skill Set Workability	Communal appraisal Reconfiguration
Investments	*Meaning*	*Commitment*	*Effort*	*Comprehension*

(May and Finch, 2009, p547)

The original construct of the NPM fitted into the fourth NPT core concept: collective action (Finch *et al.*, 2012). Collective action remained the mainstay of the NPM and continued to be used as the explanatory framework in some papers rather than NPT (Atkins *et al.*, 2011; Bouamrane, Osbourne and Mair, 2011; Forster *et al.*, 2011; Godden and King, 2011; Murray *et al.*, 2011; Spangaro, Poulos and Zwi, 2011; Ehrlich, Kendall and John, 2013). NPT has continued to evolve through a combination of its developers continuing their own work, their working with others and independent researchers using it, then this body of work being published and used to inform further development (May *et al.*, 2018).

The further evolution of ideas associated with NPT, published in 2012 by the wider team (Finch *et al.;* Mair *et al.*), develop the definitions of the concepts, and have been tabulated in Table 3-6. These publications were appearing as the study design for the example evaluation was being developed. The primary analysis adopted core concept definitions from Finch *et al.* (2012) and sub-construct definitions from Mair *et al.* (2012) (see Tables 3-5 and 3-6); however, when NPT was applied directly to the data during secondary analysis, data-driven definitions were created (see 8.2).

Table 3-6: Detailed concepts and sub-constructs of NPT

Author, date	Coherence	Cognitive Participation	Collective Action	Reflexive Monitoring
Finch *et al.,* 2012	The process of sense-making and understanding that individuals and organisations have to go through in order to promote or inhibit the routine embedding of a practice to its users. These processes are energised by investments of meaning made by participants.	The process that individuals and organisations have to go through in order to enrol individuals to engage with the new practice. These processes are energised by investments of commitment made by participants.	The work that individuals and organisations have to do to enact the new practice. These processes are energised by investments of effort made by participants.	The informal and formal appraisal of a new practice once it is in use, in order to assess its advantages and disadvantages and which develops users' comprehension of the effects of a practice. These processes are energised by investments in appraisal made by participants.
Mair *et al.,* 2012	**Sense-Making Work** *Differentiation:* Is there a clear understanding of how a new e-health service differs from existing practice? *Communal specification:* Do individuals have a shared understanding of the aims, objectives and expected benefits of the e-health service?	**Relationship Work** *Enrolment:* Do individuals "buy into" the idea of the e-health service? *Activation:* Can individuals sustain involvement? *Initiation:* Are key individuals willing to drive the implementation?	**Enacting Work** *Skill set workability:* How does the innovation affect roles and responsibilities or training needs? *Contextual integration:* Is there organisational support? *Interactional workability:* Does the e-health service make people's work easier?	**Appraisal Work** *Reconfiguration:* Do individuals try to alter the new service? *Communal appraisal:* How do groups judge the value of the e-health service? *Individual appraisal:* How do individuals appraise the effects on them and their work environment?

	Individual specification: Do individuals have a clear understanding of their specific tasks and responsibilities in the implementation of an e-health service? *Internalisation:* Do individuals understand the value, benefits & importance of e-health service?	*Legitimation:* Do individuals believe it is right for them to be involved?	*Relational integration:* Do individuals have confidence in the new system?	*Systematisation:* How are benefits identified or measured?

Another avenue May and colleagues pursued was the development of an NPT toolkit, NoMAD, to assess the target context in terms of its potential to support normalisation (May *et al.*, 2007b; Finch *et al.*, 2013; Elf *et al.*, 2018; Finch *et al.*, 2018; Rapley *et al.*, 2018). NoMAD is a questionnaire that applies the four core concepts to the environment, then produces a suitability score to guide implementers (May *et al.*, 2015); however it has not been used in this thesis.

3.5 Environment

One aspect the thesis will consider is NPT's usefulness in how it deals with the environment into which an intervention is introduced. Organisational structure and culture are part of the pre-existing environment into which complex interventions are implemented and their impact upon the process of introducing change has been recognised (Greenhalgh *et al.*, 2004; Zapka *et al.*, 2004; Sitton-Kent, 2016). There are several key aspects to environment including setting, system and population (Straus, 2009; May, 2013a; May, Johnson and Finch, 2016). Setting refers to characteristics like geographical location and type of organisation; system refers to organisational structures and population refers to groups of people affected by the intervention (Straus, 2009; Squires *et al.*, 2015a). The environment creates a **specific context** because each aspect has its own characteristics that affect an intervention and its implementation (Iles and Cranfield, 2005; Straus, 2009) (see Appendix 11.1.3). This includes organisational culture, "the beliefs that are shared by members of an organisation make up its culture … 'the way we do things round here'" (Iles and Cranfield, 2005, p74). How able an organisation is to absorb new knowledge helps to identify why an intervention is more successfully implemented in one context compared with another (Harvey, Jas and Walshe, 2015). Culture forms an 'invisible framework' or worldview that affects how employees perceive the implementation of an intervention (Iles and Cranfield, 2005). Leadership, attitudes to knowledge, learning and reliability were some elements, in the overarching context, which have been found to be influential when introducing new ideas and interventions (Evidence Centre, 2011; Harvey, Jas and Walshe, 2015). As May says: 'an innovation … is never isolated from its … contexts" (2013a, p26).

Since its inception NPM and latterly NPT and extended NPT (eNPT) have been applied across several environments (McEvoy *et al.*, 2014; May *et al.*, 2018). Developed in Newcastle, England, initially it was applied in several English settings and this continues (McEvoy *et al.*, 2014; May *et al.*, 2018). Within six years of publication NPM/NPT was being used internationally (McEvoy *et al.*, 2014). Work has principally been published from across

the UK, and other highly developed countries, such as Australia, USA, Sweden and the Netherlands (McEvoy *et al.*, 2014; May *et al.*, 2018).

NPM/NPT has been used when evaluating interventions in both primary and secondary care (McEvoy *et al.*, 2014; May *et al.*, 2018). In addition, it has been used with many healthcare and patient populations (May *et al.*, 2018). The different job roles in healthcare to which it has been applied include: general practitioners, medical and surgical consultants, practice nurses, district nurses, midwives, pharmacists and e-health service staff (Mair *et al.*, 2008; Wilkes and Rubin, 2009; Gask *et al.*, 2010; Forster *et al.*, 2011; Sanders, Foster and Ong, 2011; Ehrlich, Kendall and John, 2013; Kempen *et al.*, 2018; Sharpe *et al.*, 2018; Wikstrom *et al.*, 2019). NPM/NPT has also been applied to studies of those who experienced an intervention including: patients with – dementia, mental health conditions e.g. depression, bipolar; chronic conditions e.g. cerebral palsy, autism; chronic diseases including heart failure, respiratory diseases, diabetes; tuberculosis, infertility, children with speech and language difficulties, pregnant women, English as a second language (McEvoy *et al.*, 2014; May *et al.*, 2018). Each country has its own systems, as does every organisation; each setting and population has its own characteristics, all creating different contexts and cultures (Squires *et al.*, 2015a). The way NPT explores staff practice, context and organisational culture will be examined in Chapter 8.

3.6 Level of operation

This thesis considers the use of NPT at different levels of operation. There are four potential levels at which interventions in healthcare might operate: (1) the individual healthcare professional/patient, (2) healthcare teams, (3) organisations, and (4) healthcare systems (Alharbi *et al.*, 2014), elsewhere categorised as micro (1), meso (2, 3) and macro (3, 4) (Rousseau, 2011). NPM/NPT was conceived as working at all levels but has usually been applied at the team/organisation/system i.e. meso/macro level (McEvoy *et al.*, 2014; May, Johnson and Finch, 2016; May *et al.*, 2018). NPT has occasionally been used at the micro level i.e. with individual staff, and infrequently directly with patients (Gallacher *et al.*, 2010; Gallacher *et al.*, 2011; McEvoy *et al.*, 2014; Segrott *et al.*, 2017; Anku *et al.*, 2018; Gallacher *et al.*, 2018; May *et al.*, 2018) or with regional healthcare systems (Bouamrane and Mair, 2014a).

3.7 Critique of NPT

The attributes of NPT, found in the literature, are critiqued below by considering:

- Niche for NPT
- Strengths of NPT
- Gaps in the evidence supporting NPT
- Challenges to NPT.

3.7.1 Niche for NPT

A niche for NPT has been found in illumining the requirements for a successful process of change when implementing interventions into healthcare (May *et al.*, 2018). Previously researchers have relied heavily on using trial methodology to establish effectiveness (Moore *et al.*, 2014; Craig *et al.*, 2019). This issue, and its impact on methodology, methods and findings, was mentioned in Chapter 2. This niche has opened up an opportunity for theories which offer a framework to explain the detail of processes, rather than focusing principally on outcomes (Straus, 2009; Moore *et al.*, 2014; Morden *et al.*, 2015; May, Johnson and Finch, 2016; Craig *et al.*, 2019). NPT has been designed to consider these processes, i.e. "the work" by which implementation, embedding and integration takes place (May and Finch, 2009; Finch *et al.*, 2012). That is, the way people think and make decisions about the work of bringing in a change, the implications of those thoughts in practical terms e.g. for work practices and service delivery, and the incorporation of those activities into daily routines (May and Finch, 2009; Finch *et al.*, 2012). Applying NPT offers a new perspective from which to consider complex interventions; it enables the researcher to look for patterns amongst the factors arising during implementation that will promote understanding of the active ingredients, barriers and facilitators for the mechanisms of impact (May and Finch, 2009). This potential to bridge the theory-practice gap when scaling up will be explored in Part 3.

3.7.2 Strengths of NPT

Authors of NPT claim that it is "highly regarded" (Browne *et al.*, 2014 , p7), has been shown to be "an adequate and useful theory" and that it encompasses the "complexity of normalisation processes" (Finch *et al.*, 2012, p3; Craig *et al.*, 2019). According to the literature, NPT has many strengths when used in process evaluation (McEvoy *et al.*, 2014; May *et al.*, 2018). These include frameworks for overall interpretation and/or more specific data analysis, informing feasibility, considerable transferability between systems, settings and populations and adaptability for use with different types of intervention, different phases

of the evaluation cycle and different organisational levels (see Table 3-7). The literature reported NPT to be adaptable and to function well in the following ways:

Table 3-7: Applications for NPT

Number	Application
1	Revealing the process of change
2	Providing an organising framework for data analysis
3	Informing feasibility
4	Evaluating existing interventions for normalisation issues
5	Evaluating adoption of clinical guidelines
6	Evaluating patient-centred care
7	Transferable to a variety of environments and purposes
8	Integration with other methodologies
9	Evaluating at different time points
10	Organisational change

1. Revealing the process of change

A key aim of designing the NPM was to develop "conceptual models that provide interpretive frameworks for process evaluations [of complex interventions]" (May *et al.*, 2007b). Consequently, a principal focus when using NPT is to make explicit that which was hidden i.e. reveal "the work" that is required to successfully embed a change (Gask *et al.*, 2010; Blakeman *et al.*, 2012). In applying NPT, researchers have liked the way that it seeks to explain what, so far, has largely remained without examination; the "latent dynamics" that create "resistance" to change (Sanders, Foster and Ong, 2011, p2). This further work has tested NPM/NPT as an explanatory framework and found it to be suitable and adaptable (Gunn *et al.*, 2010; James, 2011). Later papers have continued in this vein, finding that using NPT has unmasked the central, process elements required for successful implementation (Franx *et al.*, 2012; MacFarlane and O'Reilly-de Brún, 2012; Gellatly *et al.*, 2018; May *et al.*, 2018).

Most progress has been made with the concept 'collective action' when identifying the relevant details of implementation and itemising the helps and hindrances (Furler *et al.*, 2011; Godden and King, 2011; James, 2011; Mair *et al.*, 2012). Use of NPT is beginning to build momentum and provide more examples to identify the issues common to many settings (May *et al.*, 2018). Bouamrane & Mair (2014a; 2014b; 2014c), using NPT after several years

of implementation development, seem to be reaching a point in Scotland where they have really grasped the key factors. For example: they have examined the policy context and eHealth infrastructure when introducing an integrated care pathway for surgical patients, including an eHealth form for preoperative assessment and rationalisation of clinics, across a region (Bouamrane and Mair, 2014a). They found that for a process to work well it required a structure – this can be light or more substantial (Bouamrane and Mair, 2014a). In their intervention – the Planned Care Improvement Programme - they found that without a structure it was very difficult for individual staff to effect changes of any size; the intervention offered legitimisation and therefore authority and brought resource (Bouamrane and Mair, 2014a). The external context was also crucial; local and national strategies and aligned targets pushed the implementation forward, assisted coherence and buy-in, and promoted success (Bouamrane and Mair, 2014a).

2. Providing an organising framework for data analysis

NPT has been used successfully to organise data (May *et al.*, 2018). In studies where NPM/NPT has been selected as the theoretical framework, sometimes the core concepts have also been used to create a coding frame for data analysis (May *et al.*, 2018). When using deductive, analytical methods such as framework analysis (Ritchie and Spencer, 1994), publications have often reported the findings under the concept headings then gone on to explore them in the discussion (e.g. Gask *et al.*, 2008; Wilkes and Rubin, 2009; Atkins *et al.*, 2011; Forster *et al.*, 2011; Murray *et al.*, 2011; Alharbi *et al.*, 2014). Whether used inductively or deductively, researchers are using NPT increasingly as an organisational framework for data analysis and report back positively; with findings relevant to understanding intervention and implementation processes and most, if not all, data falling within the coding frame (May *et al.*, 2018). The framework that the concepts provide for analysis were used successfully in a post-hoc analytical design by Clarke *et al.* (2014), as in this thesis. Alternatively, NPM/NPT has been used to explain the findings after inductive coding (May *et al.*, 2018).

Researchers have also explored applying NPT to their projects flexibly e.g. coding data from patients/carers to the core concepts, from which key issues for patients were identified and then presenting the issues to HCPs for comment, then coding and reporting this data to the key issues (rather than the core concepts) yet using NPT as the overarching explanatory framework (Browne *et al.*, 2014). Another example was to use NPT to understand the perplexing results from a trial where no benefit had been seen from an intervention (Clarke *et al.*, 2013; Clarke *et al.*, 2014).

3. Informing feasibility

NPT can be used to explore feasibility of an intervention, or the implementation plan, in ways that increase the likelihood of success by sensitising the stakeholders to the issues (Murray *et al.*, 2010; Morden *et al.*, 2015). Finch *et al.* (2012) talk about the notion of 'fit' and stated that "'normalisation' is considered to be an ongoing cycle of activity aimed at making a new practice 'fit in' with the work of individuals and their context of practice" (p3). NPT would be an appropriate framework to apply when using qualitative methods in feasibility studies for RCTs, as exemplified by Steele *et al*. (2019), who used NPT when uncovering mechanisms and informing programme theory before conducting a trial into an electronic patient-reported outcome tool.

Chiang *et al.* (2015) report another example of using NPT to consider the feasibility of a cancer risk assessment tool for General Practitioners (GPs). They found a likely hindrance was how doctors preferred to rely on their clinical intuition rather than the tool's risk output (Chiang *et al.*, 2015). Another group of researchers developed a delirium prevention programme in acute care based on their feasibility study using NPT (Godfrey *et al.*, 2013). While Gask *et al.* (2010) used the NPM/NPT to identify key care components when designing a collaborative care model for patients with depression. In another study, NPT was used pre-trial to inform the development of a training intervention for WISE, a programme to assist in self-care support for people with long term conditions (Kennedy, 2010). However, to date, NPT has not been widely used to assess feasibility.

4. Evaluating existing interventions for normalisation issues

NPT has been employed to evaluate existing interventions e.g. if uptake is lower than expected following implementation (May *et al.*, 2011b; Murray *et al.*, 2011). Many studies across a wide variety of health contexts have used NPT successfully to explore the reasons behind the gap between expectations and real practice, using either primary or secondary analytical methods (May *et al.*, 2018). For example: when quality of care was a concern in mental health care delivery, NPM was used to explore how well governance measures were being integrated into processes (Gask *et al.*, 2008). Elwyn *et al.* (2008) explored why decision aids for collaborative decision-making between practitioners and patients were not being used routinely. Wilkes & Rubin (2009) were interested to find out why access to hysterosalpingography had not become established. While Furler *et al.* (2011) analysed the reasons for delayed initiation of insulin treatment for patients with diabetes. Macfarlane & O'Reilly-de Brún (2012) reflected on the low uptake of interpreters in GP practices with non-English speaking patients and Forster *et al.* (2011) considered why a model for delivery of

maternity care was discontinued after appearing to be trialled successfully. Uptake of a screening tool for domestic violence amongst pregnant women was low, so Spangaro, Poulos and Zwi (2011) investigated the reasons using NPT. Similarly, when public dissatisfaction was expressed for national speech and language services, NPT was used to unearth the background to this response (James, 2011).

5. Evaluating adoption of clinical guidelines

An early use of NPM was to explore the adoption of evidence-based guidelines, especially when implementation was problematic, and unpick the factors that impeded this process (Gask *et al.*, 2008; Morriss, 2008). Researchers have since found NPT to be well suited to this application (May *et al.*, 2018); the originators have reviewed the literature more recently and identified five factors that dispose guidelines towards being normalised, outlined in May *et al.* (2014). In a similar vein, Bamford *et al.* (2012) found that the basic tenets of NPT were not met when implementing nutritional guidelines for elderly people in care homes. Indeed, a significant finding from Beenstock *et al.* (2012), that led to the implementation of babyClear©, was that uptake of NICE PH Guidance (2010) was inconsistent.

6. Evaluating patient-centred care

This was a minor theme in the literature. Mostly "the work" associated with bringing in a change has been studied in relation to practitioners or occasionally managers (May and Finch, 2009; Alharbi *et al.*, 2014; Segrott *et al.*, 2017); however, some papers reveal how, indirectly, this is closely related to patient-centred care (Elwyn *et al.*, 2008; Sanders, Foster and Ong, 2011; Godfrey *et al.*, 2013). Patient-centred care or patient involvement in changes to care were found to be lacking in telecare (May *et al.*, 2011b) and clinical decision-making (May, 2013a). For example: when considering preventing delirium in acute care, it became clear that many of the recommendations would be incorporated if high quality, patient-centred care was given (Godfrey *et al.*, 2013). Elwyn *et al.* (2008), in their study on collaborative decision-making tools, found that the "asymmetries of power and knowledge" (p1) between practitioners and patients explained much of the difficulty in normalising the tools. Similarly, Sanders *et al.* (2011) found that GPs did not prioritise patients with non-specific, low, back pain and were confident that they knew how to assess and treat it using standardised methods. As a result, Sanders *et al.* (2011) concluded that GPs were closed to using a new assessment tool or recommending different treatments e.g. more and earlier referrals to specialist physiotherapists. The authors found that, for several reasons, largely related to threats to their clinical freedom, this resulted in less personalised, patient care (Sanders, Foster and Ong, 2011). More recently, Goldthorpe *et al*. (2018) included

interviews with patients, as well as providers and practitioners, to explore implementation of an electronic referral management system in oral surgery using NPT.

7. Transferable to a variety of environments and purposes

NPT appears to have considerable transferability. NPM/NPT was first applied to e-health interventions and has continued to be used in this field (McEvoy *et al.*, 2014; May *et al.*, 2018). Since 2010, NPM/NPT has been applied to an increasing number of intervention types (McEvoy *et al.*, 2014; May *et al.*, 2018). It now appears that it has stood the test of time in these terms and has been reported as suitable for multiple healthcare settings and interventions (May *et al.*, 2018). This trend to use NPT widely across health contexts and specialties has continued and is increasing (e.g. Gellatley et al., 2018; Kempen et al., 2018; Sharpe *et al*., 2018; Wilkstrom *et al*., 2019).

8. Integration with other methodologies

NPT has been used successfully with other methodologies and methods, but the authors do not claim that it is an evaluation method or directly concerned with effectiveness itself (May and Finch, 2009). The approach relies on other methods to deliver outcomes information; thus, NPT has been used in primary, mixed method studies (May *et al.*, 2011a; Watson *et al.*, 2011; Finch *et al.*, 2012; Franx *et al.*, 2012; Blickem *et al.*, 2014) and single method, qualitative studies to explain the processes that produce the outcomes (Atkins *et al.*, 2011; Gallacher *et al.*, 2011; Blakeman *et al.*, 2012; Steele *et al.*, 2019). NPM/NPT has also been used for secondary analysis - as the framework to analyse literature, either in the feasibility/scoping phase of primary data collection or for an independent review:

Example 1: Elwyn *et al.* (2008) successfully dived under the surface of the known barriers to the use of decision aids in healthcare and made explicit some of the more hidden aspects that people tend to keep secret, such as aids were time-consuming to use and contradict the maximum efficiency goals of organisations; they require the HCP to spell out the uncertainties to patients, which they were not always comfortable in doing; decisional responsibility begins to lie more with the patient, and therein lies the responsibility for HCPs to make this clear and not all patients want to shoulder that responsibility.

Example 2: Godden & King (2011) appraised feasibility when they examined the potential for introducing telehealth to support primary care respiratory medicine by accessing Quality and Outcomes Framework data and disease registers. They found that knowledge of patient distribution was required, due to its impact on feasibility, and that the capacity and attitude of

both individuals and organisations influenced the success of implementation (Godden and King, 2011).

Example 3: Watson *et al.* (2011), in their review, assessed models of transitional care for young people with complex needs. Using NPT as a framework clearly identified how the literature focused on collective action, but was largely lacking in coherence, cognitive participation and reflexive monitoring. This allowed the authors to identify the gaps in terms of service development and evaluation of services.

Increasingly now NPT is being taken by researchers and used in new ways alongside other approaches and methods e.g. behaviour change approaches, realist evaluation and co-creation (Hannigan *et al.*, 2018; Herber *et al.*, 2018; Lewis *et al.*, 2018).

9. Evaluating at different time points

NPT is recommended for use at different time points within the evaluation cycle i.e. formatively and/or summatively (Moore *et al.*, 2014; May *et al.*, 2018), including post-trial. For example: following on from NPT based findings at the feasibility stage, analysis of post-trial data allowed for comparison between expected and real-life scenarios, when assessing the feasibility of new interventions (Gask *et al.*, 2010; Kennedy, 2010; Green *et al.*, 2015).

10. Organisational change

NPT can be used to investigate behaviour change beyond the individual level (May and Finch, 2009). Although individual practitioners make the choices and the changes it is recognised that they work within groups/teams and in an organisational context (Finch *et al.*, 2012; May, Johnson and Finch, 2016). Finch *et al.* (2012) explain that, “In NPT it is postulated that practices become routinely embedded in social contexts as the result of people working, individually and collectively, to enact them, and that the production and reproduction of a practice requires continuous investment by individuals to carry action forward in time and space” (p2). There are an increasing number of examples of how NPT has been used in this broader, organisational context and they demonstrate the importance of a whole-systems approach (Goldthorpe *et al.*, 2018; Carstensen, Brostrom Kousgaard and Burau, 2019; Wikstrom *et al.*, 2019).

3.7.3 Gaps in the evidence supporting NPT

The literature about NPT has been growing and the theory continues to develop: however several areas of continuing uncertainty remain (May, 2013a; 2013b; May, Johnson and

Finch, 2016; May *et al.*, 2018), reflective in part of the general lack of systematic review of applying complexity and systems theory to evaluation rather than NPT *per se* (Walton, 2016). They fall into two categories where evidence is lacking: theoretical and empirical, as in Table 3-8.

Table 3-8: Gaps in the evidence for NPT

Number	Issue
Theoretical	
1	Limited evidence about capturing fidelity
2	Limited evidence about demonstrating sustainability
Empirical	
3	Limited evidence about transferability to other settings
4	Limited populations studied

1. Limited evidence about capturing fidelity

Fidelity is not an issue widely discussed in the NPT literature; instead papers focus on understanding process, not compliance *per se* (McEvoy *et al.*, 2014). Bouamrane & Mair (2014a) and other papers being published by this team (2014b; c), considered standardisation vs adaptability, with its implications for fidelity. They found that structure, usually in the form of a guideline or directive, offered a plan to follow and implement (Bouamrane and Mair, 2014a). It was not necessarily totally rigid and may allow for local adaptation; but the broad structure that enabled and legitimised the change, thus prioritising and resourcing it, was the necessary element for fidelity (Bouamrane and Mair, 2014a). There is room for more exploration of the intervention elements that are core i.e. are fundamental to the effectiveness of the intervention, and those which are desirable but optional (Escoffery *et al.*, 2018).

2. Limited evidence about demonstrating sustainability

The early published literature around sustainability in studies that have used NPT as their framework are scant; perhaps relating to the concentration on action and lack of focus on fidelity (May *et al.*, 2018). Franx *et al.* (2012) identified the lack of appraisal systems or consideration of the broader context as weaknesses in the intervention under study. A large, mixed-method study, designed to address this general gap in systematic reviewing of healthcare implementations, by Aarons *et al.* (2014), might offer insights when it reports. Another potential avenue might be interpreting NPT findings through the lens of

organisational culture change literature, like that published by Willis *et al.* (2016) to complement findings in 'reflexive monitoring'. The poor record in sustainability of many complex innovations was flagged up by the developers of NPT, and recently in MRC guidance (May *et al.*, 2018; Craig *et al.*, 2019). A minority of studies published more recently are using NPT to look into sustainability and investigate the challenges to normalisation (Carstensen, Brostrom Kousgaard and Burau, 2019; Walugembe *et al.*, 2019; Wikstrom *et al.*, 2019).

3. Limited evidence about transferability to other settings

To date, NPT has primarily been used in the NHS in England and the key papers are authored by a coterie of researchers (McEvoy *et al.*, 2014; May *et al.*, 2018); however, this is changing. NPT is increasingly being used by researchers beyond this group and beyond the UK (Anku *et al.*, 2018 - Ghana); (Conn *et al.*, 2015 - Canada); (Ehrlich, Kendall and John, 2013 - Australia); (Foss *et al.*, 2005 - Norway); (Holtrop *et al.*, 2016 - USA); (Shemeili *et al.*, 2016 - Abu Dhabi); (Trietsch *et al.*, 2014 - Netherlands). The review of papers citing NPT, was published by the developers but with the expressed inclusion of new members and actions taken to reduce bias (May *et al.*, 2018). Nevertheless, there is a potential for positive bias; indeed, in a previous review, all the papers do report NPT generously (McEvoy *et al.*, 2014). The team has gone out proselytising by deliberately welcoming other researchers to try out the theory and has worked alongside others (McEvoy *et al.*, 2014; May *et al.*, 2018). It remains to be seen the extent to which NPT is transferable to other healthcare systems and countries; however, the results reported to date look promising (May *et al.*, 2018).

4. Limited populations studied

Most papers on studies using NPT are concerned with practitioners, because they report on investigating implementation of innovation in clinical practice and service delivery from a staff viewpoint (May *et al.*, 2018). For a long time, there was only one paper published where NPT was used to directly study patients; it involved treatment burden for people with chronic heart failure, which the team have now followed up with more papers (Gallacher *et al.*, 2010; Gallacher *et al.*, 2011; May *et al.*, 2014; Gallacher *et al.*, 2018). Gallacher *et al.* (2011) found that the line between individual staff and patients was finely drawn, in that the researchers noted how the similarities/ commonalities within the idea of 'work' between patients with chronic conditions and that of staff was marked. Management of the complexity of treatments and medications, expected by health professionals of the patient, echoed the complexity of operationalising initiatives in practice scenarios (Gallacher *et al.*, 2011).

Gallacher *et al*. (2018) concluded that the patient capacity for 'work' influenced the level of care that they were able to achieve.

Within the NPT literature, principally practitioners and a few patients have been considered as individuals, but it is not clear how the level of operation (individual/team) has been integrated at the population level (Elwyn *et al.*, 2008; Kennedy, 2010; Gallacher *et al.*, 2011; Sanders, Foster and Ong, 2011; Blickem *et al.*, 2014; Segrott *et al.*, 2017). However, understanding both the patient perspective and the environment at every level is critical in understanding the overall normalising of an intervention (Iles and Cranfield, 2005; May and Finch, 2009; Straus, 2009). McNaughton (2017) has based her doctoral thesis at the individual, patient and HCP level. She found that NPT assisted in identifying the social influences and HCP attributes that affected patient responses to the offer of NHS Health Checks (McNaughton, 2017). Anku *et al*. (2018) similarly included patients, as well as practitioners and providers, in their study of combining tuberculosis and HIV services in Ghana. These are areas ripe for further study.

3.7.4 Challenges to NPT

Beyond the gaps in the literature there are various challenges that have arisen; sometimes in response to NPT and at other times general to the field. The ones of interest to this thesis are outlined in Table 3-9.

Table 3-9: Challenges to NPT

Number	Challenge
1	Clarity of definitions
2	Suitability for purpose
3	Linearity/iterative nature of implementation
4	Embracing organisational and system context
5	Context and individuals
6	Organisational/frontline-clinical contexts
7	Eliciting mechanisms of impact
8	Integrating with logic modelling

1. Clarity of definitions

In an evolving field new terms are being coined to represent new ideas; however, this has led to confusion about meaning (Papoutsi *et al.*, 2016; Walton, 2016). Closer definition of

new terms and concepts and exploration of their borders and areas of overlap is required (Papoutsi *et al.*, 2016; Walton, 2016). On the cusp between the model and the theory Bouamrane, Osbourne and Mair (2011) brought out a paper applying them both to the same data, resulting in combining the constructs and concepts. Based on conference proceedings, it reviews progress so far and seeks to inform the readership about this development in thinking through application (Bouamrane, Osbourne and Mair, 2011). This overview was confusing to read, partly because the concepts shade into one another as they morph from one stage into another. Care is required in defining terms as accessibly as possible for a general readership. The question remains as to whether the model continues to have currency and/or if the theory has superseded it.

A slightly different issue, the overlapping of meaning and allocation of codes to NPM constructs and latterly NPT concepts, has been raised (McEvoy *et al.*, 2014). This has made them difficult and confusing to use on occasion (Gunn *et al.*, 2010; Atkins *et al.*, 2011; Sanders, Foster and Ong, 2011; Franx *et al.*, 2012; McNaughton, 2017). Macfarlane & O'Reilly-de Brún (2012) argued that this was the nature of enquiry into complex interventions; however, for a theory to be applied consistently and comprehensively a common understanding is required. Higman *et al*. (2015) may already be a casualty of this type of thinking; their paper states that NPT is the theoretical framework but there is no discernible relationship to the concepts reported in the findings. Most recently, in a review of papers using NPT, comments on terminology were mentioned as a criticism of the theory (May *et al.*, 2018). It outlined decisions researchers had made to overcome this difficulty, including re-interpreting or newly describing the constructs from their data (May *et al.*, 2018).

2. Suitability for purpose

The suitability of NPT is gradually emerging. The original model, with its focus on collective action, has been reported most frequently (McEvoy *et al.*, 2014), as it takes some years for researchers to apply new theories to new studies and publish them (Atkins *et al.*, 2011; MacFarlane and O'Reilly-de Brún, 2012). In their review, McEvoy *et al.* (2014) commented on the way NPT had been applied but also noted a) the way that collective action dominated and b) concepts had been used selectively by some researchers. An early paper on applying NPT by Sanders *et al.* (2011) focused on ‘coherence’ as they did not find their data mapped onto the other concepts. They suggested this was due to their population of GPs not finding the intervention coherent i.e. they did not get past the first requirement for successful implementation (Sanders, Foster and Ong, 2011).

Three papers stand out as choosing NPM over NPT for their analysis (Ehrlich, Kendall and John, 2013; Henderson and Rubin, 2013; Hoberg *et al.*, 2013). Ehrlich *et al.*(2013) state their reasons as: “The broader NPT is concerned with the macro environment within which complex interventions are implemented, whereas the original model focused on the micro conditions of everyday practice and considers how people make complex interventions workable ... In this study, we were focused on understanding the micro conditions of everyday practice” (p129). Henderson & Rubin (2013) and Hoberg *et al.* (2013) do not specify why they reported only on ‘collective action’ from NPT. The former two point out its usefulness in identifying the likelihood for normalisation of the study intervention and the latter focus on feasibility and sustainability of the intervention rather than taking a more holistic view of implementation analysis (Ehrlich, Kendall and John, 2013; Henderson and Rubin, 2013; Hoberg *et al.*, 2013). This raises the question of the cohesiveness of NPT, if concepts can be left out at will. However, it may not necessarily be a negative reflection on NPT, it may be more about the evolution of thinking; maybe NPT really has something to offer here, to bring balance and holism to the whole process as compared with prioritising the obvious activity. Franx *et al.* (2012) sound a cautionary note, that glossing over ‘coherence’ and ‘cognitive participation’ and jumping into ‘collective action’ too soon or failing to ‘reflectively monitor’ could be detrimental to continuous quality improvement.

3. Linearity/iterative nature of implementation

NPT is explained as iterative rather than linear (May *et al.*, 2007a), however theory-users such as Alharbi *et al.* (2014) describe the concepts as a linear process over time. Sanders *et al.* (2011) state an intervention must be coherent first, but Blickem *et al.* (2014) see NPT as useful in looking at non-linear progress towards implementation, with concepts being present simultaneously rather than sequentially. This issue is picked up by May *et al*. (2018) who recognise that a linear approach has often been appealing to researchers. They also note that for studies that focus on pre-implementation, this is often so (May *et al.*, 2018). For studies focusing on collective action i.e. the main implementation phase, however, they suggest, a simultaneous approach is more acceptable.

4. Embracing organisational and system context

Process evaluation, using qualitative methods, is commonly seen as one way to address some of the issues surrounding variable contexts that are not suitable for controlling in trials (see Chapter 2). As the promise of process evaluation of complex interventions has grown, so has the demand for understanding and answers, and with it, recognition of the central role of context (Shoveller *et al.*, 2016; Orton *et al.*, 2017). Understanding the role of context

variables and their impact on implementation continues to be a challenge (Moore *et al.*, 2014). Shoveller *et al.* (2016) found that by opening 'the black box' through making detailed notes and understanding the context, complex interventions were less likely to fail.

Context has many aspects e.g. economic, environmental, social and political, leading to suggestions that a systems approach is an appropriate perspective to evaluate complex interventions (Greenhalgh *et al.*, 2004; Moore *et al.*, 2014; Orton *et al.*, 2017). A systems approach sits well with NPT as it incorporates some contextual elements within its core concepts, however it could be argued that NPT still does not draw in enough context (May *et al.*, 2018); that although sociologically based it focuses too narrowly on collective action or it varies depending on the level of operation (individual, team, organisation, system), breadth and depth of the enquiry (see Chapter 9). This exposes the study to the likelihood that some contextual factors will fall out of scope (Franx *et al.*, 2012). Most publications report comparatively small-scale studies so far (May *et al.*, 2018); to discover how well NPT copes with the many aspects and levels of organisational and system context and their impact on an implementation further study is required.

5. Context and individuals

A separate body of work has been published which focuses on individual behaviour change (Michie *et al.*, 2005; Michie, van Stralen and West, 2011; Michie *et al.*, 2013). This acknowledges that people are placed within contexts e.g. home, family or employing organisation, and that all contexts have their own norms (Michie *et al.*, 2005). NPT recognises that practitioners bring their own, unique selves to their jobs but also work in system contexts that influence their behaviour (May, 2013a). These contexts within a work environment might release or constrain staff actions (Michie, van Stralen and West, 2011; Finch *et al.*, 2012; Michie *et al.*, 2013). Indeed, the NPT toolkit was designed to be applied before any interventions were tried, to consider the context for implementation and show the need for changes that would enable normalisation (May *et al.*, 2011a; Bamford *et al.*, 2012; Bamford *et al.*, 2014). The extent to which NPT incorporates individual context successfully is yet to be established; however, it relates to how well NPT closes the theory-practice gap.

6. Organisational/frontline-clinical contexts

The level of operation for NPT was envisaged as collective and organisational (meso) rather than individual (micro) (May and Finch, 2009). Studies have proliferated which have brought together the individual staff and meso/macro context levels (McEvoy *et al.*, 2014). This has created tension between collecting data from frontline workers (micro) yet focusing the

model at the system level (macro) (Spangaro, Poulos and Zwi, 2011). This was identified as problematic by Hall *et al.* (2016), in that NPT was not found to be specific enough in relation to individuals, to explain the process of changing organisational culture to allow for normalisation. Boaz *et al.* (2016) had already argued that the next step to Diffusion of Innovation Theory-based thinking was to get down to the detail, rather than remain at a general level, so that the impact of activities of key individuals could be clarified. This organisational/frontline-clinical contextual divide has not always been easy to integrate in meaningful analysis (Mair *et al.*, 2012). May has taken up this apparent theory gap when postulating eNPT (2013b). He accepted that individual agents have the potential to significantly affect change, as much as collectives, and explored the boundaries between them (May, 2013b). The interplay between NPT and individual behaviour change requires further enquiry (May *et al.*, 2018).

7. Eliciting mechanisms of impact

As NPT has evolved, so has the realisation that eliciting mechanisms of impact was vital to embedding interventions (Pawson and Tilley, 1997). May (2013b) perceived them as essentially social but Pawson and Tilley (1997) state them more broadly e.g. physical, chemical or biological alterations that lead to social and psychological shifts in perception. Moore *et al*. (2014) see them as partly participant responses, to be captured by qualitative methods, and then combined with quantitative data. However, the principle remains, that by identifying the mechanism researchers can understand the process of implementing, integrating and embedding more fully (Pawson and Tilley, 1997; May *et al.*, 2009; May, 2013b; Kreindler, 2018). Although mechanisms are mentioned in early NPM papers, moving to a clearer Theory-of-Change-type concept on mechanisms is a relatively recent departure for NPT (May, 2006; 2013a). ToC links closely to logic modelling (W.K. Kellogg Foundation, 2004) - combining logic modelling and NPT is explored in Chapter 7 and is a specific contribution to knowledge claimed for this thesis.

8. Integrating with logic modelling

NPT is likely to be well placed to coalesce with logic modelling as the theory has been widely used to inform evaluation of implementation and identify helps and hindrances to normalisation (Atkins *et al.*, 2011; Bouamrane, Osbourne and Mair, 2011; Franx *et al.*, 2012). Logic model methodology is used to articulate the programme's ToC (W.K. Kellogg Foundation, 2004). Central to effective use of logic modelling is identifying the active ingredients and mechanisms of impact (W.K. Kellogg Foundation, 2004; Rogers, 2007). Potentially normalisation issues could be re-framed to explain the transitions between

phases in a logic model (W.K. Kellogg Foundation, 2004). Applying NPT in this way could assist in articulating the ToC of a complex intervention more explicitly. These ideas are explored in Chapter 2, used during secondary analysis (Chapter 7) and discussed in Chapter 9.

3.8 Recent developments in NPT

NPT is continually evolving and being moulded by new knowledge which challenges it to become increasingly accessible and useful (May, 2013a; 2013b; May, Johnson and Finch, 2016). May continues to publish on NPT, drawing primarily on sociological and psychological theories (2013a; 2013b; 2016; 2018). May has suggested extending it to a general theory of implementation, aiming for greater comprehensiveness beyond healthcare settings (May, 2013b). This was always the developers' intention, for it to move beyond healthcare to other settings (May and Finch, 2009; May, 2013b). They have been expanding the theory in terms of being relevant to any innovation socially situated within a system i.e. suggesting that the social processes that are active during implementation and embedding are not specific only to healthcare (May, 2013a; 2013b).

1. Extended NPT

The areas of the general theory that are of interest to this thesis are the 'contribution', which contain the original four core concepts of NPT, and the social mechanisms i.e. the processes that deal with unpredictable contexts and contingency (May, 2013b). Social mechanisms, in this paper, are defined as: a 'process that brings about or prevents some change in a concrete system' (Bunge, 2004). May has begun to explore the characteristics of mechanisms that are most likely to enable normalisation; namely plasticity and elasticity (May, 2013b). May and colleagues develop their ideas about these characteristics in their paper published in 2016, wherein he postulates eNPT; extending the theory to include plasticity - defined as: 'the extent to which users can mould [complex adaptive systems] to fit a particular context' and elasticity – defined as: 'the extent to which users can mould elements of the environment to allow a set of intervention components the space to work'. This takes May into the debate over the influence of context in real-life scenarios (May, Johnson and Finch, 2016).

Two papers have been published to date (21st May 2019) using eNPT (Drew *et al.*, 2015; Segrott *et al.*, 2017). Drew *et al*. (2015), while generally complimentary, encountered some of the same challenges concerning overlap of constructs with eNPT as mentioned when using the NPM and NPT. They found that conducting an initial, inductive thematic analysis to

NPT constructs before coding to eNPT constructs assisted analysis (Drew *et al.*, 2015). Segrott *et al*. (2017) report how they used eNPT to examine intervention-context interactions to explain variation in how an intervention was implemented. This provided useful contextual evidence to inform the results from the concurrent RCT; thus, moving towards translating research knowledge into practical application and narrowing the theory-practice gap (Segrott *et al.*, 2017). These ideas have yet to be widely applied.

2. Publication of systematic review

In June 2018, once this thesis was nearing completion, a systematic review was published (May *et al.*) – including papers dated up until December 2017 - citing NPT. It mirrors the questions and findings of this thesis in many ways, including its key results relating to claims about NPT:

1 … accurately depicts important elements of implementation processes
2 … provided conceptual tools … successfully explained [study] outcome[s]
3 … can be applied flexibly … [used] by researchers and practitioners with diverse professional backgrounds … [in a] variety of healthcare settings.
(May *et al.*, 2018)

This is reassuring as it increases the trustworthiness of this study's findings (Lincoln and Guba, 1985). However, importantly, there are no publications exploring combining NPT with logic modelling, as in this thesis (May *et al.*, 2018). Nor is there a discussion specifically about using NPT to narrow the theory-practice gap; although it does point to the lack of use of theory generally in implementation research (May *et al.*, 2018).

3.9 Neglect of knowledge translation

In England, under successive governments, the pressure to evaluate what works and what is cost-effective has been driving theoretical and methodological thought forward (Blamey and Mackenzie, 2007; Shepherd, 2014); although the ability to systematically review the evidence to understand programme theories is still in its infancy (Maden *et al.*, 2017). There is no direct evidence in publications to date (21st May 2019) of NPT being linked with knowledge translation (KT) (May *et al.*, 2018). May *et al*. (2007a) aspire to provide 'transparent and transferable explanations', however, rarely do the papers by May and colleagues mention KT *per se*. Rather bizarrely 'knowledge translation' is referred to in the abstract of May *et al*. (2016) but then left unmentioned in the text; simply referring in the conclusion to 'translational efforts' of scaling interventions up and out (p9).

KT, where research findings are moved into practice, is not a theory; however, it is a consideration in achieving expected outcomes (Tansella and Thornicroft, 2009; Kitson *et al.*, 2017). There are challenges in communicating knowledge and implementing it into real-life contexts (Tansella and Thornicroft, 2009; Squires *et al.*, 2015a). Greenhalgh *et al*. (2004) referred to how knowledge needed to be enacted, constructed and shared before it could be used to bring about change (p588). Evaluation Support Scotland (2012-2019) define KT as, "making sure that evidence [i.e. theory] is available and accessible for the people or organisations that need to understand or use it" (words in brackets added).

KT is inherent in taking research evidence and academic knowledge forward and embedding it into policy and practice; however, concern has been expressed around the process of translating it effectively (May and Finch, 2009; Shepherd, 2014; Fuse - the Centre for Translational Research in Public Health, No date). In terms of making evidence usable, policy makers, practitioners and systematic reviewers, in their separate ways, require information with a broader scope to be able to apply the findings accurately (Moore *et al.*, 2014; Shepherd, 2014; Craig *et al.*, 2019). This is where non-experimental methodologies can make a significant contribution in translating and transferring knowledge; by capturing perceptions and addressing contextual issues that are answered using non-experimental methodologies - sometimes with a complementary trial design (Moore *et al.*, 2014).

Taking the topic of KT to a more individual, staff level, some work by Wenger (2009) has come to prominence. He coined the phrase: "communities of practice" which he characterised as a group of people which: has a shared domain of interest, interact and learn together and share a practice (Wenger, 2009). All these characteristics provide structures for informal learning (Wenger, 2009). Again, this theory has links to normalisation and how new interventions become embedded within a service (Sitton-Kent, 2016). These theories are of interest to this thesis because they sit closely with the aims and constructs of NPT (see Chapter 3). They offer examples of moving knowledge effectively from the 'ivory tower' onto the frontline (Straus, 2009; Ogilvie *et al.*, 2011; Salter and Kothari, 2014; Squires *et al.*, 2015a). Various routes continue to be explored (Rushmer *et al.*, 2015; Sitton-Kent, 2016). This thesis will look at how NPT contributes to this endeavour.

Going one step further, Rushmer and colleagues (2015) looked to co-creation of knowledge to increase effectiveness and overcome some of the difficulties associated with KT, especially in public health. A key idea in co-creation is that research is carried out with participants not done on or to them, in recognition that people are not passive recipients in

many cases of interventions/services but active actors who make choices (Rushmer *et al.*, 2015). KT is a "social and dynamic process" and will be operating at many levels, including amongst communities of practice, but knowledge may not necessarily flow easily across boundaries (Wenger, 2009; Rushmer *et al.*, 2015). Rushmer *et al*. (2015) posit that co-creation is one way to improve KT; however, they point out that it can also be a challenging process to carry out.

Even so, the reporting of process evaluation remains underprivileged, with outcomes evaluation data still dominating in published articles (e.g. Grant *et al.*, 2013; O'Cathain *et al.*, 2013). The effect is notable in the criteria for journal publication which is often skewed towards a trial design, for example in the lower word count, the reference to 'results' rather than 'findings' and the structure of articles, all of which sit more easily with an experimental approach (Charmaz, 2012). This has an impact on KT, a relatively new field, which, like non-experimental methodologies, is having to make the argument to be accepted as a legitimate area of research (Kitson *et al.*, 2017).

In the conclusion of May, Johnson and Finch's paper (2016), developing ideas around the relationships between implementation, context and complexity, they mention the potential for KT. How to translate academic knowledge, into a clinical environment, in the most appropriate ways remains under development (Kitson *et al.*, 2017). In May *et al*. (2018) he talks about NPT being a 'conceptual toolkit' to 'deal with practical problems' that relate to solving 'problems in intervention design and evaluation'. Schloemer & Schröder-Bäck (2018) go further and identify the information required from the primary and target contexts for successful transfer of complex, public health interventions. Their review reports the necessary normalisation factors and creates a model to gather the information systematically (Schloemer and Schröder-Bäck, 2018).

3.10 Conclusion

The literature published on NPT to date demonstrates how this theory is not inviolable and has benefited by remaining susceptible to critique and evolving as it has been applied (May, 2013b; May, Johnson and Finch, 2016; May *et al.*, 2018). This chapter has outlined how NPT has developed in response to an acknowledgement of a gap in terms of understanding the process of implementing complex interventions. This has been attributed to an over-reliance on evidence based, experimental designs. The constructs of NPM and the core concepts of NPT have been examined in relation to their use in understanding the real-life scenarios of implementation processes and how they interact with the intervention. The way

in which NPM and NPT have spread out across the research world has been explored. A synopsis of the strengths of NPT and the remaining gaps and challenges in the published evidence has been presented. As a relatively new theory working into a changing environment, both in terms of research and healthcare, as well as politically, economically and socially, there remains much to be done to develop its full potential, especially in KT. However, its strengths outweigh its limitations for this purpose and justify its use in this study.

3.11 Chapter summary

This chapter has examined both the historical development of NPT and the range of environments in which NPT has been used. It has then critiqued the attributes of NPT noted by authors during its use to date. The chapter has provided a basic understanding of the theory and how it relates to the underlying issues with which this thesis contends, including the effect of organisational culture and context on normalisation. Justification for choosing NPT is explored through identifying the various ways it can be applied.

This introduction to NPT has found that:

- NPT is a tool to equip clinicians and researchers to work together to improve interventions and their implementation
- NPT is built out of pre-existing sociological and psychological theories with rigorous testing of constructs and subsequent concepts
- Exploring environment is central to using NPT
- Since its inception NPM and latterly NPT and eNPT have been applied across an increasingly wide variety of systems, settings and populations
- NPT is a niche theory that illumines the requirements for a successful process of change when implementing interventions into healthcare
- Using NPT offers many strengths during process evaluation, including frameworks for overall interpretation and/or more specific data analysis, informing feasibility, considerable transferability between systems, settings and populations and adaptability for use with different types of intervention, different phases of the evaluation cycle and different organisational levels
- Remaining challenges need to be addressed through more work by research teams independent of the theory developers into a) defining the terms more clearly; b) determining if NPT meets its stated purpose; c) settling conditions of linearity; d)

applying NPT to more systems, settings and populations and e) exploring fidelity, mechanisms, context and sustainability as described by Moore *et al.* (2014)

- Recent developments include a paper on eNPT (May, Johnson and Finch, 2016) and a systematic review (May *et al.*, 2018)
- Neglect of using NPT for knowledge translation continues.

PART 2

This section consists of Chapters 4 and 5, covering the methodology and method, and outlines a methodology consonant with the argument developed in Chapter 2. It pursues the idea that an alternative theoretical and methodological approach to the RCT is required if the theory-practice gap is to be understood. In Chapter 4, I put forward a theoretical base and methodology that, I suggest, can comprehend more adequately the factors which influence effective implementation and sustainability, than is possible with an evaluation design founded solely upon controlled experiments. I preface this suggested approach by an explanation of its socially constructed ontology and interpretivist epistemology. Chapter 5 takes up the narrative by giving the details of the method I employed during the process evaluation. It was data collected during the process evaluation that I used for the secondary analysis. Findings from this analysis are described in Chapters 7 and 8, in answer to the research questions, repeated below:

Research questions

To meet the aim of the thesis the research questions (RQs) consider: -

1) To what extent does the NPT framework successfully allow:
   a) identification and
   b) elaboration
   of the process of normalisation of a complex intervention?

2) To what extent does the NPT framework assist in understanding:
   a) feasibility and
   b) fidelity
   whilst allowing interventions to be adapted to the needs of the complex systems in which they operate?

3) To what extent does the NPT framework assist in understanding:
   a) sustainability and
   b) transferability when scaling up to population level?

Chapter 4 METHODOLOGY

4.1 Introduction

This chapter begins by stating the epistemological and ontological position of the thesis. I then discuss the adopted ontology, social constructionism. This builds on the theoretical proposition introduced in Part 1; that study designs may legitimately be non-experimental and data analysis can be subjective and interpretive, depending on the knowledge that is the goal of the research question. This reflects a change from widely-held and previously accepted research practice in public health, as explained in Chapter 2. Being mindful of the components of the research process identified by Rose (1982), my aim is for the reader to understand how NPT slots into the development of thinking about public health complex intervention methodology, and how the debate concerning the perspectives that underpin the operationalisation of the methods, affects this study. Field-work and results are covered in Part 3.

4.2 Philosophical underpinning

4.2.1 Ontological position

Ontologically, in this thesis, I take a realist position, in the sense that reality is understood as being socially constructed and, to some extent, relative (Berger and Luckmann, 1991). The phrase 'social constructivism' was coined by Berger and Luckmann, in their treatise first published in 1966 (1991). It drew on several sociological theories to create a new perspective that has since become well-established and popular; it has provided the building blocks for subsequent theorisation (Berger and Luckmann, 1991; Vera, 2016). Fundamentally it envisages the definition of society as being variable according to an individual's views; views which themselves are derived from the communal knowledge people have gained through life (Vera, 2016).

Constructionism is a different term, but one which is often confused with and used interchangeably with constructivism, however its meaning is distinct (Vera, 2016). Constructionism, according to Crotty (1998) relates to the idea that groups of individuals construct how society is to be understood, rather than individuals alone.

Crucially a socially constructed ontology does not try to control the context and its impact on the intervention package and process; instead it allows for a full appreciation of the influence of multiple contextual variables (Berger and Luckmann, 1991). This fits well with the

evaluation's theoretical underpinning which "focuses on what people do - their agentic contributions to the social processes by which innovations are implemented, embedded and integrated in their social contexts" (May, 2013a, p25). How the nature of reality is viewed is fundamental to what is produced by the research process, because it determines how the issue is perceived and framed, leading to decisions about the methodology and methods to use (Crotty, 1998; Cresswell and Poth, 2018). Research based on a realist ontology uses interpretive methodologies to answer its questions; so, for example, it will be interested to know about people's feelings and interpretations of events and will be framed from the participants' perspective (Crotty, 1998).

4.2.2 Epistemological position

Epistemologically I have taken the view that reality is subjectively experienced; consequently, people's thoughts, feelings and behaviours influence the nature of reality i.e. how people react to the stop smoking referral pathway in babyClear© will determine its effectiveness (Wellington *et al.*, 2009). So, what a member of staff or a pregnant woman's epistemological position is (for example, what they believe about smoking or quitting) is the truth as they understand it (Berger and Luckmann, 1991). Their position is likely to have been shaped by their personal circumstances, whether it be gender, age, ethnicity, social class, education, housing, family norms, working norms and many other circumstantial and environmental factors (Wellington *et al.*, 2009; Vera, 2016). This is an important issue, as their epistemological position influences both their individual and group behaviour (Berger and Luckmann, 1991; Wellington *et al.*, 2009).

4.2.3 Applying social constructionism using NPT

There is a wealth of literature stretching back over many years, which is used to explain the reasons for the theory-practice gap between research results and real-life outcomes when introducing complex interventions (e.g. Tansella and Thornicroft, 2009). Indeed, this literature has been systematically reviewed and guidance developed by the MRC, as discussed in Chapters 1 and 2 (2000; Craig *et al.*, 2008; Craig *et al.*, 2009; Moore *et al.*, 2014; Craig *et al.*, 2019). The chosen epistemology, social constructionism, may be used to view this theory-practice gap (Crotty, 1998). It is sympathetic to a realist ontology and epistemology and takes a subjective, interpretive perspective to research, focusing on an individual's learning through social interactions (Crotty, 1998; Bryman, 2012). As such, I would argue, that it has the potential to reduce the theory-practice gap.

When applying a social constructionist approach, it is expected that an intervention will not work out the same every time; it is accepted that the process will be influenced by multiple aspects of the context into which it is being implemented, and in this sense, is relative (Berger and Luckmann, 1991). It is recognised that the activity of human agency and social relationships can change the process and findings (Wellington *et al.*, 2009). Researchers employing a process evaluation are more concerned with answering the questions of process i.e. how and why an intervention works and in what context, rather than being focused on enumerating effectiveness outcomes. Thus, social constructionism is sympathetic to process evaluation methods (Moore *et al.*, 2014; Cresswell and Poth, 2018).

Similarly, NPT is consistent with social constructionism since context, holism and the importance of making explicit the processes that were hidden or secret, are central to the theory (see Chapter 3). Fundamental to the evaluation is understanding the context and process and unearthing the mechanisms of action, change and impact (W.K. Kellogg Foundation, 2004; Bryman, 2012; O'Cathain *et al.*, 2013). Only then can intervention effectiveness be maintained during transfer or scaling up (Moore *et al.*, 2014).

In contrast to process evaluation and NPT, epistemologically the example intervention is at odds with social constructionism. This thesis has argued that a subjective ontology is required as the example intervention relates to public health with the typical attributes for its type; however, the intervention uses a service delivery model, common to English public services, that involves professionals as experts who bring their expertise to service users (Eckley, Ruddick and Walker, 2015). This manner of delivery sits most neatly with the scientific, positivist view of reality rather than one that is relative and socially constructed i.e. the receivers are not part of creating the solution (Eckley, Ruddick and Walker, 2015). It espouses a method which has been criticised for focusing on the problem, separating supporters from supported, discouraging positive relationships and entrenching power hierarchies (Eckley, Ruddick and Walker, 2015). There is, therefore, a fundamental contradiction within the example intervention, in terms of the epistemology and ontology versus service delivery model and outcomes.

4.2.4 Choice of method for data collection

Interpretive frameworks demand qualitative methods of data collection and analysis because these methods answer the questions that are being posed and provide the knowledge that is sought (Cresswell and Poth, 2018). They principally include observation and individual and group interviews in some format, although documents and other artefacts and records may

be examined (Cresswell and Poth, 2018). Occasionally these may be complemented by quantitative methods; however, this is a hotly debated topic (Marchal *et al.*, 2012; Bonell *et al.*, 2013; Marchal *et al.*, 2013; O'Cathain *et al.*, 2015; Bonell *et al.*, 2018; Sandelowski, 2018; Vogl, 2018). To answer the research questions posed, it is appropriate therefore, that the process evaluation methods included observational and interview data collection (Maxwell, 2013).

4.2.5 Conclusion

Methodologically and ontologically this thesis views reality as socially constructed. Consequently, it accepts that individual and group responses to the implementation and intervention may vary, and in so doing, alter the outcomes in many ways that are difficult to control and measure empirically. The theory I am using, NPT, a mid-range theory that is based on the idea that reality is socially constructed, explores normalisation processes from this viewpoint. However, I suggest that babyClear© is more positivist in design and less sympathetic to a socially constructed understanding of the processes and mechanisms. Nevertheless, I argue that the choice of method for the thesis should be consistent with the philosophical underpinning of the research.

4.2.6 Summary

This chapter has explored the theory and theoretical perspective underlying the thesis. I have adopted a subjective, constructivist and interpretivist stance, which will be used to explore the utility of NPT in the study example.

Chapter 5 METHOD

5.1 Introduction

This chapter is concerned with the method used for the process evaluation of the implementation of babyClear©, or, as Rose (1982) would have it, operationalisation and field-work, that is, ensuring consistency between all aspects of the study design, so that the methods are integrated into the whole. The research questions of the evaluation example require qualitative data to answer them, as they are looking for expressions of people's experiences and opinions of the normalisation process, rather than looking for cause and effect, as in experimental methodologies. Therefore, the evaluation is based on a constructivist, interpretivist methodology; the benefits of which, when evaluating the implementation of complex interventions in public health, are discussed in Chapter 2. These methodological choices are important to the thesis because the evaluation provides the data for the secondary analysis. An account of the subsequent analytical work and findings, specifically for this thesis, including the preparation and conduct of the secondary analysis, can be found in Part 3.

5.2 Evaluation design

5.2.1 Scoping

Initially a scoping exercise was undertaken with managers in the maternity and stop smoking in pregnancy services who were part of a steering group for the process evaluation. I contacted them to find out their employing organisations' structures and asked them to identify key members of staff within their organisations. This included talking to the maternity matron in the Trust where the implementation was most advanced. I discussed plans for the evaluation with her, especially the suggested recruitment procedures. I followed up this scoping with an email to the staff member acting as a champion for the intervention, introducing the research team and discussing possible data collection methods. These conversations were replicated in all Trust areas. They were also designed to identify the specificities of the local maternity and SSPS delivery models. I drew up diagrams of each local model and sent them to the key informants to confirm or amend, so that the organisational structures and planned service delivery pathways were clear to me before starting to collect interview data. Key informants functioned in a variety of roles e.g. public health midwives, SiP specialists, and worked within a variety of service delivery models.

5.2.2 Public and patient participation

As part of designing the research tools, I established a panel of mothers who had smoked in pregnancy prior to the introduction of babyClear©, with the support of a colleague. We recruited them from mother and toddler groups in two locations (A and B) with different socio-demographic profiles. In Location A, the LA has the largest proportion of highly deprived neighbourhoods in England (49 per cent) including the area of recruitment, whereas in Location B, the LA is ranked 33rd out of 326 and the area of recruitment reflects this position (Department for Communities and Local Government, 2015, p10, 14). We met four times with two groups of four mothers, one group from each location. Service user involvement was used to sensitise me to the issues from a public and patient perspective.

5.2.3 Ethical considerations

Approval was given by Teesside University's School of Health and Social Care, Research Governance and Ethics committee on 5th June 2014 (Study number 038/13) for data collected during the evaluation of babyClear© to be used for an academic purpose (Appendices 11.3.1). According to the Integrated Research Application System definition of studies this natural experiment was examined using a 'service evaluation'. Appropriate governance approval was secured from all study sites.

5.3 Methods

Rigour in qualitative research

Rigour is necessary if the results of research are to be reliable (Bryman, 2012). Critics of qualitative methodology have tended towards scientific method to ensure rigour (see 2.3), however Guba & Lincoln and others have argued for alternative guiding principles (1985; Ritchie and Spencer, 2012). They established the criterion of trustworthiness, rather than validity and reliability, in qualitative data as: credibility, dependability, confirmability and transferability (see Table 5-1) (Lincoln and Guba, 1985; Ritchie and Spencer, 2012).

Table 5-1: Criteria of trustworthiness

Credibility	Can the findings themselves be believed and also how were they reached?
Dependability	Are the findings consistent? Could the analysis be repeated?
Confirmability	Do the participants accept the veracity of the findings?
Transferability	Could the findings be applied to other contexts?

(Ritchie and Spencer, 2012, p231)

Data collection methods:

a) field diary

b) observation of training sessions

c) individual and group interviews with members of staff and patients.

Rationales for data collection methods

Field diary

A field diary acts as a chronicle of the research journey. The researcher records what happened from their perspective and includes a detailed summary of behaviour and events, including their reflective comments and initial analytic thoughts (Bryman, 2012). It acts as an *aide memoire* when reviewing the project and is an adjunct to the data collection and analytical processes (Bryman, 2012). It is recommended that notes are made as soon as possible after the event or thought (Bryman, 2012).

Non-participatory observation

Observation is a qualitative method that uses the researcher as a tool to note down, for study purposes, what they are observing in a field setting (Cresswell and Poth, 2018). Observational methods can have varying degrees of involvement by the researcher, from high to low; with non-participatory methods, as used in this study, classed as a low level of involvement (Spradley, 1980). It can also be used to complement other methods, triangulate the data and inform the researcher about attitudes and inter-relationships from a different perspective (Maxwell, 2013). Note-taking can take several forms e.g. structured coding sheets, more flexible descriptive and reflective logs and/or observational field notes (Bryman, 2012; Cresswell and Poth, 2018).

Interviews and focus groups

A constructivist, interpretivist epistemology requires a qualitative approach, such as interviews (Lincoln and Guba, 1985). They can vary in the level of structure used, from fully to semi to unstructured interviews (Bryman, 2012). Less structure allows the conversation to roam around the topic, gives more choice and freedom to the participant(s) and tends to build greater rapport between the participants and interviewer (Bryman, 2012). Less structure tends towards more rich, detailed data; however, a semi-structured approach is more focused and therefore has the practical benefit of taking less time and resource than completely unstructured interviewing (Bryman, 2012).

Recording and transcribing

Digital audio-recording of interviews with individuals and groups has the advantage of providing an accurate, permanent record of tone and content, with the option to thoroughly re-examine the data at leisure (Bryman, 2012). Further, the researcher is not distracted by note-taking, can concentrate on the questions and other researchers can check the recordings (Bryman, 2012). Recording and transcribing ensures the analyst has a thorough familiarity with the text and it increases transparency, as it allows others to check the research process (Bryman, 2012).

Reflexivity

To be reflexive is to recognise my own pre-conceptions, perspectives, strengths and shortcomings and be aware of how I, as a researcher, interact with the research process; specifically, how my beliefs and views affect study design, data collection and analysis (Ritchie and Spencer, 2012). In qualitative methods the researcher is the research instrument and so, in a sense, requires a high level of reflexivity and fine tuning to do the job well (Maxwell, 2013). As I reflect over my life, I can see some areas that are relevant to this study, such as my upbringing, my nursing career, my faith and life priorities, which I will now comment on.

My upbringing was in Surrey, in a wealthy area, as part of the aspiring middle-class. I was the first generation to be privately educated and second generation to go to university. Initially I trained as a registered nurse. My training included a 3-month placement in a maternity unit, moving between antenatal clinics and the labour ward. I clearly remember, with a mixture of terror and fondness, the day I was ‘the runner’ for a caesarean section operation. This involved standing at the door ready to fetch and carry for those gowned up in theatre. At other times I was trying to witness enough ‘normal deliveries’ to fill my notebook. Sometimes the ward was quiet and there was little to do, other times it was busy and exciting. My first staff nurse position was on an oncology ward in 1981. I worked as a member of a team, both on oncology wards and in clinics, and latterly as the lead, over the following 5 years. These memories of training, what it was like working on a maternity unit, dealing with patients, leading a team, enabled me to build bridges to healthcare staff during data collection, through this common bond of experience. I had learnt how to have conversations, both with staff and patients, touching on sensitive subjects, approaching people empathetically and sympathetically. Skills which I could draw upon during interviewing.

My outlook on life affects everything; my own life choices and ultimately my attitude towards smoking, and specifically SiP. It influenced my choice to leave behind my wealthy, childhood, environment - with its money-making priorities - and move to one of the poorest regions in the country and prioritise supporting those born into less privileged circumstances. Much of this I have done via the local church, for example: supporting those without homes, those trapped in addiction and those living in precarious financial circumstances. This has brought me into contact with many people living in deprived circumstances, similar to the majority of those who smoke while pregnant. Learning about their stories, their hardships, has put into context for me, their smoking behaviours.

My husband and I had one child. We decided to stay in the area as a matter of principle, with all the environmental and educational limitations this incurred. Later, we adopted two more children to complete our family. This has taken us deep into the world of children in care, and all the associated challenges they, and the families they come from, face. I think this has developed my understanding of how children growing up in highly dysfunctional families have to find ways to cope with the damage present in their lives. The specific circumstances, and level of neglect and abuse they experience, vary, but the consequence - separation from their birth mother - is common to all adoptive children. They are then left to work out how to deal with the damage dealt to them in their early years, throughout the rest of their lives. This has created in me a determination, when I engage with those from homes where children are neglected and abused, to support them into responsible adulthood, where they are able to make healthy decisions for themselves, and not default to thinking that results from damage sustained as a child.

After a period of 15 years at home, nurturing my three children, I chose to study for a degree in line with my prioritisation of supporting others. I completed my BSc in Public Health and Well-being in 2006. I took up work in research immediately afterwards and I went on to study for a master's degree in Public Health Sciences, passing with distinction. I have a track record in evaluating nursing and public health interventions and previously evaluated a stop smoking intervention in acute care. I carried out the day-to-day running of these projects including the data collection and analyses. In the main, these have been qualitative studies. Evaluating babyClear© was my most recent project when I was offered the opportunity to use the data from it to pursue this doctoral study. These are the 'facts' which are likely to colour my view in this study.

Reflexivity has allowed me to step back and check my perspectives, motives and practice. I recognise that the topic of the thesis appealed to me because it potentially equips HCPs to increase their effectiveness. It does this by exploring a mid-range theory and its utility in allowing us to think about implementation. Being self-aware and recognising how I, as the researcher, affect other people, is essential in collecting and analysing qualitative data (Lincoln and Guba, 1985; Ritchie and Spencer, 2012). I need to remain aware of the personal lens I am using – new mother, experienced mother, grandmother, friend, nurse professional, researcher. Using self-awareness and empathy I probed during interviews and sought to understand the data accurately in analysis (Lincoln and Guba, 1985; Ritchie and Spencer, 2012). Interviewing requires a reciprocal relationship to develop between the participant(s) and the interviewer (Maxwell, 2013). Ideally, from my point of view, it results in rich data which will produce answers to the research question(s) (Maxwell, 2013); it is not for me to become involved more deeply in their lives, even if I feel a pull to do so.

A reflexive approach is needed to anticipate and overcome issues, acknowledge the complexities of researcher/participant relationships and reduce barriers in a variety of ways (Maxwell, 2013). I noted in myself, that through my work and life experience I easily developed rapport with people, then I would begin to empathise with them. Due to my outlook on life, I wanted to be part of helping them solve their problems and promote their health and happiness. I wanted midwives and stop smoking staff to be enabled in their work and pregnant smokers to be supported to quit, believing it to be in their best interests, while understanding their contrasting beliefs. I was aware of wanting the intervention under evaluation to do well, to be successful in terms of outcomes, while recognising the need for impartiality. I can see that my concern for deprived communities led me to the importance of recognising the role of context in behaviour change, at all levels. This is worked out in the thesis through the logic model, introduced in Chapter 6, and findings in Chapter 7 (see 7.2 – 7.5).

From a positivist standpoint, these emotions could be construed as a form of bias and a threat to external generalisability (Maxwell, 2013). Indeed, evaluating without some consciousness of my own position can blur or narrow my vision; therefore, a reflexive stance is vital (Ritchie and Spencer, 2012; Maxwell, 2013). To address this threat, data collection and analysis processes were made explicit to establish rigour and trustworthiness (Lincoln and Guba, 1985; Ritchie and Spencer, 2012) and assist me in highlighting any personal bias.

One further consideration from a reflexive stand point, regarding ethical practice, is a recognition of power hierarchies (Thompson and Chambers, 2012). I am female, in common with most of the participants, however I was not an employee of the services being evaluated, so there were no organisational rivalry or status issues; however, the outcome of the evaluation was likely to have an impact on practice. Potentially staff could be unwilling to change their behaviour as required by the intervention. In addition, staff who were being evaluated were likely to feel that their practice was being checked for compliance. With this comes the possibility that they may be found wanting or in error. So, I could be seen as representing change, and depending on how they felt about the changes they were being asked to make, they may react towards me accordingly.

Senior managers held higher positions in the management hierarchy in their organisations compared to mine at the university. These people would be my 'natural' superiors at work and yet I needed to meet with them in such a way that they would offer me their honest and insightful answers, not simply tow the party line or play political games. I was of a similar age to senior managers which seemed to help them to perceive me as experienced and with a maturity that made me likely to understand the issues.

5.3.1 Sample selection

Training sessions

Training was designed for all staff who would be implementing a part of the package i.e. midwives, MCAs, SSPS advisors and administration staff. Aims and objectives of the training focused on changing HCPs' discourse and attitude towards pregnant women's smoking as well as developing skills to deliver the intervention (Appendix 11.4.1). In terms of skills, the training covered the first brief intervention by maternity staff, scripting of telephone calls from the SSPS, CO monitoring by HCPs, RPT from a midwife and a variety of ongoing, follow-up options provided by various staff.

There were four types of training session aimed at the different staff groups i) community midwives (2 hours), ii) stop smoking advisors (1 day or 2 day), iii) stop smoking administrators (½ day) and iv) RPT midwives (1 day). Training consisted of lectures, practical skills, group work and role play, using multiple learning styles. It was presented as a standard package based on a specific service delivery model. The sessions were carried out centrally with the expectation that trainees would travel to the location.

Once ethical approval for the process evaluation had been gained, a convenience sample of training sessions (n=11) among those remaining to be delivered, was chosen for observation (see Table 5-2). A series of prompts were used for the observations (Appendix 11.4.2).

Table 5-2: Number of training sessions observed

Trainee session type	Length of session	Number of sessions observed
Maternity staff (midwives and MCAs)	2 hours	6
RPT midwives	1 day	1
SSPS* specialist advisors	1 day	3
SSPS pharmacists	1 day	1

*Stop Smoking in Pregnancy Service

I conducted all the observations and in total I observed 157 staff during training. I chose a selection of different types of training session designed for a variety of roles, run at times when I was available; however, it was not possible to observe an administration staff session, or the longer training for SSPS specialist advisors (2 day), either because I was unavailable, or the sessions had already been completed or did not run. Sessions taking two days were cancelled by the trainers due to lack of uptake. This was reported to be due to a combination of the significant time away from clinical care and the perceived benefit i.e. it was aimed at specialist advisors who, in this region, already had high levels of experience. It was assumed there would be repetition from previous SS training and the time investment was not worth it. I understood some of the pressures on staff to prioritise completing their work over training, especially if its benefit was being questioned, from running outpatient clinics myself.

The target of training all maternity and stop smoking in pregnancy services staff who would be instrumental in implementing the intervention was not fully met in every Trust area and some areas achieved greater coverage than others. This was related to the amount of facilitation provided by senior managers e.g. giving permission for attendance and making it feasible while still covering the workload. I understood how, without senior management support, it was impossible for some staff to comply with accessing training; however total numbers of staff eligible for training were not available. For the total number of staff trained see Table 5-3.

Table 5-3: Number of staff trained

Role	Maternity staff	Risk Perception Tool midwives	SSPS* specialist advisors	SSPS pharmacists	Admin -istrators
Trained	293	8	104	31	28

*SSPS = Stop Smoking in Pregnancy Service
Source: Improving Performance in Practice (IPiP)

Interviews

The sample of participants for interview was selected purposively from individuals involved in delivering the contract for training, or organising, implementing and/or delivering babyClear© in the NE region.

Inclusion criteria:
a) managers within maternity and stop smoking in pregnancy services
b) frontline staff within maternity and stop smoking in pregnancy services who had received the babyClear© training
c) babyClear© trainers
d) babyClear© lead in Fresh NE.

Senior managers, maternity and stop smoking in pregnancy services staff participants were recruited purposively according to their roles. Other participants were recruited from those who had been trained in delivering babyClear©.

The interview sample comprised 102 staff, namely:
Senior maternity managers (n=8)
Midwives (n=42); including 2 public health midwives
MCAs (n=13)
SSS staff (n=32); employed by LAs; including 9 managers
Pharmacy staff (n=3)
BabyClear© trainers (n=3)
BabyClear© lead in Fresh NE (n=1).

5.3.2 Data collection

Data collection methods in practice

In this intervention example, observation allowed me to see how the individuals and the group related to one another, to the trainer and the trainer's message (Bryman, 2012). It also

gave me first-hand knowledge of what was being taught and its fidelity to the stated aims. I, as a trainee nurse, had experience of transferring information taught in the classroom to real-life, on the ward or in the clinic. Many of my most dramatic experiences took place during my maternity placement. Seeing babies born, reacting in emergency situations when baby or mother were threatened, as mentioned in 5.3 (reflexivity). More recently, I had experienced being taught research methods, then going into the field and facing many challenges that were not fully addressed during teaching. In relation to translating knowledge about SiP into enabling behaviour change, I was aware of pregnant smokers at hospital entrances, as I was on-site collecting data. In spite of clear, smokefree signs, patients were continuing to smoke. I felt uncomfortable at the thought of challenging their behaviour, even when the environment claimed to be supportive. In common with the midwives, I felt the conflict, knowing how detrimental smoking is to maternal and perinatal health, and wanting to warn women, but at the same time uncertain about how to phrase the smokefree message in an acceptable, non-judgemental, non-paternalistic and effective way. Observational data was collected with these thoughts in mind; it informed the interview questions and allowed for assessment of the fidelity with which the package was implemented compared to the training given.

Observations

Prior to observing a session, I spoke to the trainer in advance and on the day, then made myself known to the group. I chose as unobtrusive a place as possible to sit as dictated by the setting's seating arrangements; sometimes at the back behind trainees or to the side. Sitting behind had the disadvantage of not being able to see the trainees faces and observe their facial reactions to the training; however, it might have helped trainees to forget they were being observed. It also put me in the place of a trainee with the trainer possibly more conscious of my presence and making her aware that she was being observed. When sitting to the side of the trainees, I sensed their reactions more easily, but remained more observable myself.

I took a copy of the explicit aims of the training session and the broad topic schedule for interviews with me. The former prompted me to keep in mind how the session met its aims and the latter prompted me to think about how the data would fit into the NPT core concepts. A template to record observations of the sessions was drawn up (Appendix 11.4.2) which allowed me to be flexible in my note-taking.

Development of data collection tools

Topic guides based on NPT core concepts were written in discussion with the research team (Appendix 11.4.3). Looking primarily from an HCP perspective for staff interviews, I took each NPT core concept and identified a series of questions relevant to the study topic and research questions, using the sub-constructs for guidance. NPT, by its definition as a mid-range theory, is less academic and closer to practice on the ground, than a purely theoretical series of concepts (May and Finch, 2009). This allowed me to apply the concepts and sub-constructs more readily to the data collection tool. Rose (1982) talks about 'concept-indicator links' (p20), which express the relationship between theory concepts and data collection tools and emphasises the importance of ensuring that the tools collect the data that will answer the RQs. For examples of concept-indicator links, see Appendix 11.4.4.

I adapted the schedules for each role type so that the questions were appropriate. These questions acted as flexible topic guides. The schedules were designed to be incorporated into conversational interviews, rather than used as a strict question sheet. I incorporated input from the service user panel into them, as mentioned in 5.2.2. I modified the schedules in response to early findings from the observational and interview data (Appendix 11.4.5). I used the first interviews to pilot the questions. I continued to ask the same core questions throughout; however, I changed the wording of awkward questions and added emerging issues to later interview schedules. Sometimes questions had to be adapted to consider the variety of service delivery models across the region, and especially the allocation of functions to different roles.

Accessing participants

I was introduced to senior managers in maternity and stop smoking in pregnancy services by the lead manager in Fresh NE, who had pre-existing links with them and co-ordinated the training and roll-out. I accessed frontline staff via their senior managers. For maternity staff this was the Head of Midwifery (HoM) in the first instance, cascading down information about the study to their team managers, usually via email. For SSS staff, employed by LAs, this was their senior manager, who again cascaded information down to their staff. I interviewed all those who contacted me agreeing to take part.

I followed up pharmacy staff who had received babyClear© training with a request to participate in the evaluation, using the contact details they had provided to the training organisation. As part of agreeing to the training they had been made aware by the training organisation that the intervention would be evaluated. Contact details for seven trainees

were forwarded, five of whom I was able to contact, but the contact details were no longer current for others (n=2), due to changes in employment. Of those I contacted successfully, three agreed to be interviewed. I approached all the babyClear© trainers and the lead in Fresh NE purposively (due to their roles), all of whom agreed to participate.

Interviewing

Interviewing involves a specific skill-set: namely the interviewer must be able to set the interviewee at ease yet draw rich data from them; to steer the conversation yet be flexible; to be alert to probe further; and to be able to sum up the discussion (Bryman, 2012). The interview may range over various experiences and opinions, flexing according to the interviewees' contribution, with the interviewer gently bringing the conversation or discussion back on topic or probing any interesting, new directions (Bryman, 2012).

In deciding whether to conduct individual, dyad or larger group interviews I was conscious that staff time was precious and bounded by a variety of limiting factors, which varied according to roles, e.g. clinic times, community visits, number of patients on caseload and management meetings. Therefore, I offered participants a choice over the type of interview they preferred.

Individual interviews, compared with dyads or larger groups, have different characteristics (Bryman, 2012). It was important to recognise this and for me to adapt my interviewing technique accordingly. Participants may feel 'in the spotlight' and feel greater pressure than in a group, reacting with discomfort or overcompensating out of embarrassment (Bryman, 2012). Interviews with one individual do not have any peers or group members to question or corroborate the views expressed, so there can be a greater possibility of self-report bias (Maxwell, 2013).

Dyads and larger groups, while similar in terms of flexibility of topic, offer different data to individual interviews in that they permit discursive interaction between group members (Krueger and Casey, 2015). The interviewer is in a less powerful or influential position, being outnumbered by the group (Krueger and Casey, 2015). Established groups know one another well and, depending on pre-existing relationships and hierarchies, are more likely to feel more - or less - comfortable sharing their views (Krueger and Casey, 2015). The role of the interviewer becomes that of moderator, keeping the discussion moving and relevant, while encouraging engagement from all participants (Krueger and Casey, 2015).

A moderator team (moderator and assistant) is recommended to manage a larger group, as one person cannot give the attention required to each member (Krueger and Casey, 2015). This was not possible in this study and is therefore a limitation in data collection. I had to take care of the environment, logistics and recording and make session notes as well as concentrate on the discussion (Krueger and Casey, 2015). In addition to basic interviewing techniques, the moderator needs to be sensitive both to individual needs and group dynamics (Bryman, 2012). One of the greatest challenges in larger groups is to limit the dominance of a few and draw out the quieter members, giving all members the opportunity to express their views (Bryman, 2012).

Semi-structured interview schedules

Data were collected through the use of semi-structured schedules containing questions covering specific topics (Bryman, 2012) (Appendix 11.4.3). A semi-structured method was considered preferable and appropriate to answer the research questions and elicit participants' perspectives and opinions; it offered flexibility in terms of asking the questions and allowing the conversation to flow while recognising staff and researcher's time limitations (Bryman, 2012). The topics and questions were the same for frontline staff, whether individual or group interviews, as I wanted to cover the same issues; however, I phrased the questions slightly differently, as appropriate for the number of people. I adapted the questions for senior managers, trainers and the lead from Fresh NE (Appendix 11.4.5).

Conducting data collection

Key informants typically were interviewed alone, as they tended not to have peers, and introducing them into a group would create power hierarchies, which would be likely to limit and bias the data (Thompson and Chambers, 2012). Although I conducted group interviews alone, they were with established groups, such as maternity teams, who were on their own territory. They knew one another and the setting well and were used to working as a team. Team leaders were sometimes present, potentially changing group dynamics and affecting the data (Bryman, 2012).

I carried out all the interviews for the process evaluation. I have a background in nursing and was able to use my knowledge of hospital systems, procedures and care of patients to empathise with maternity staff participants; also making it clear at the outset that the interview could be stopped at any time e.g. if the participant was upset or had to leave e.g. due to demands of work. I aimed to be sensitive to power hierarchies, to meet clinical staff at a peer level (partly through my nursing and public health experience), and to offer some

reciprocity in terms of information for those who were curious about the evaluation and what was happening elsewhere in the region (Thompson and Chambers, 2012). I tried to allay suspicion and fear and build rapport by approaching staff with genuineness and deference (Thompson and Chambers, 2012).

One hundred and two staff participated in all (see 5.3.1). As part of data collection, I recorded participants' job titles. Within the list of staff participants there was considerable variation in roles and responsibilities. In some Trusts a midwife carried a specific public health remit and promoting the stop smoking agenda would be their responsibility. These roles however varied widely e.g. people operating at varying levels of authority, in departments of different sizes, given responsibility for differing issues and given different priorities. Some Trusts employed MCAs, others did not, and some had more than others. The stop smoking responsibilities of the MCAs also varied between Trusts, from places where it was central to their role and highly prioritised, to those where the stop smoking function was subordinate to breast feeding and other public health topics. In some areas the person carrying out the public health role regarding SiP was employed by the LA SSS and worked in collaboration with maternity services. Likewise, pharmacies were being promoted as a setting for stop smoking in pregnancy follow up in some areas, but less so in others.

Data collection was carried out on work sites. Only people's work locations and roles were recorded; no demographic data were requested, although many participants referred to their length of service during interviews. Staff were primarily seen in individual interviews (n=34), sometimes with two members of staff together (n=16) or in larger groups (n=11); the decision being based on participant preference, convenience and availability. Team members who did not want to take part busied themselves elsewhere. The length of interviews varied, with recordings of individual interviews ranging from 20 – 92 minutes and group interviews from 13 – 85 minutes. Most interviews were digitally recorded; exceptions were made at participants' request and the conversation was noted instead (n=2). One participant engaged in conversation by email and another by telephone with the researcher. These involved a short correspondence and did not contain new information but confirmed details collected in other face-to-face interviews.

Senior maternity managers (i.e. HoMs, maternity matrons) were interviewed face-to-face, individually, in six of the eight Trusts. I arranged telephone interviews with the two remaining, one of which took place, but the other was missed by the participant.

Similarly, I interviewed senior SSS managers face-to-face, either in groups or individually. One carried responsibility for three Trusts. Also, one took part in a group interview with team members initially and then was re-interviewed 10 months later, after they moved to a SSS in a neighbouring area. I interviewed advisors among the SSS staff and pharmacy staff individually or as groups within their teams, as preferred by the participants.

In addition, I interviewed four people separately, due to their roles in initiating and implementing babyClear©. One was from Fresh, the NE's tobacco control programme; one was from the Tobacco Control Collaborating Centre (hosted by IPiP), the collaboration which won the contract to deliver babyClear©; one was the originator of the babyClear© approach and the lead trainer, and the fourth was the only other trainer.

Delay in conduct of interviews

Trusts did not implement the intervention in the expected order or pre-specified timeframes, as set out in the original implementation plan. Individual and group interviews were intended to follow the randomised, cluster roll out of the intervention. Interviewing staff was due to begin in later implementing areas then return to the early implementing organisations, to gain a linear perspective and understand the situation once it had been implemented for a longer period. I collected data throughout the implementation period; despite the very large number of interviews, data saturation was not reached, in as much as contexts were in constant flux and implementation was incomplete in some areas.

Data saturation is a means of reducing bias and establishing trustworthiness (DePoy and Gitlin, 2005). Without it the risk of bias increases because many voices remain unheard (DePoy and Gitlin, 2005). There is always the potential for important information to be missed, but more so if any participant groups are unrepresented. In this study, fewer interviews were conducted in Trusts that struggled to establish the intervention. This could have led to unrealistic expectations relating to the ease of implementation or gaps in understanding barriers, especially those that proved to be immovable.

By remaining aware of these risks, and integrating other, supplementary measures, bias can be minimised. In this study, as I became increasingly concerned about the delays in implementation and their effect on the plan for data collection in WP2, I focused on five supplementary measures: i) using triangulation between transcripts, ii) ensuring that interviews took place in every Trust (regardless of implementation status) and iii) interviewing as late in the implementation process as practical. Fourthly, I collected data in a

different order to the plan, reflecting the differential rate of progress with implementation, to give the maximum opportunity to reflect back on the process. Fifthly, I increased the number of staff interviews overall.

These supplementary measures contributed towards reducing risk of bias, although data saturation was not reached. I was able to use the flexibility inherent in observational methodologies to adapt my interview timetable. I knew that all Trusts had found implementation more challenging than expected, so there was plenty of data recording the common barriers; however, I needed to remain open the possibility of missing data.
Interviews were audio-recorded digitally. In this study I was not focusing on language so verbatim transcription of dialogue was sufficient; however, if there were significant sounds e.g. lengthy pauses, angry tone, or difficulty in hearing the words, they were alluded to at the transcriber's discretion. Certain conventions were observed e.g. indicating missing words (Bryman, 2012). I transcribed some recordings and others were transcribed by an external agency, but all were checked for accuracy, screened for consistency and anonymised by myself. To maintain anonymity, confidentiality and to comply with data protection laws the recordings, transcripts and analysis were carried out and stored according to the ethics application.

In addition, I entered notes into an electronic field diary throughout the evaluation. These included data that was not captured by any other means but that the researcher thought might carry significance, especially relating to context. I recorded the research process and especially my experiences of data collection and analysis. Sometimes these were factual descriptions of what happened; at other times they were more opinionated or reflexive. Notes were made as soon as possible e.g. sitting in the car after observing each training session, on return to the office after an interview, or on coming off the telephone in the office. I recorded information about the broader context that was not being picked up through direct interviews; for example, media items and off-the-record conversations.

Anonymity and confidentiality

The data were anonymised and stored confidentially (e.g. by separating participants' names and other identifying details from their data, allocating non-identifiable numbers and using secure storage technologies) (Thompson and Chambers, 2012). These methods were stipulated in the participant information sheets (Appendix 11.3.3). Care was taken when using quotes in reporting and dissemination, so that they could not be attributed to an

individual by those who knew the organisations well; although individuals were informed that they might recognise their own words or those of others, so that anonymity could not be absolutely guaranteed. Similarly, measures were taken to protect participant confidentiality, including storage of documents and keeping discussion of data within the study team.

Informed consent

In this study, when observing training sessions, it was agreed that individual consent was not required as I was not identifying individual trainees. Ethical approval stipulated that I would ask for permission from the trainer to sit in and observe, would make myself known to the group and indicate my purpose there, at the beginning of the session, and make it clear that I would not be collecting data on any individuals, but only on the group.

Flexible logs, field notes and schedules were the recording methods I employed during observation of training sessions. I was mindful of the ways to watch, listen and note what I observed (Appendix 11.2.3). I used these different types of information and recording formats to capture varying aspects of the observations. To maximise accuracy, I took a reflexive stance and purposively selected a variety of training session types. Sessions were mandatory for staff and pre-arranged by Trust managements, rather than self-selected by trainees.

I discussed the details of the study with interview participants; offering an opportunity to read the information sheet and time to decide if they wanted to take part prior to seeking written consent (Appendix 11.3.4). Participants were able to choose not to be recorded and given the opportunity to see and/or withdraw their data on request within a limited timeframe (Thompson and Chambers, 2012). If participants had become distressed, they would have been offered the option to curtail the interview; however, this did not arise. In this case, support from clinical supervisors for staff would have been made available.

5.3.3 Data analysis

One way to understand this analytical process is to accept that there are “three sets of orders”: the physical data, the researcher and the method of cataloguing, which feed into analysis, and which together constitute more than the separate parts (Crang, 2003). Crang (2003) contends that already the researcher has intervened and begun analysis by structuring the data simply through the storage process. He continues by saying that the activity of the researcher is to reconfigure and shape it to produce new meaning (Crang,

2003). This is the art, the creative act of the researcher, that interprets the data, connecting and dividing ideas, juxtaposing and re-ordering it to make data speak to other data in new relationships (Crang, 2003). By this activity of destruction and reconstruction the researcher crafts new interpretations (Crang, 2003).

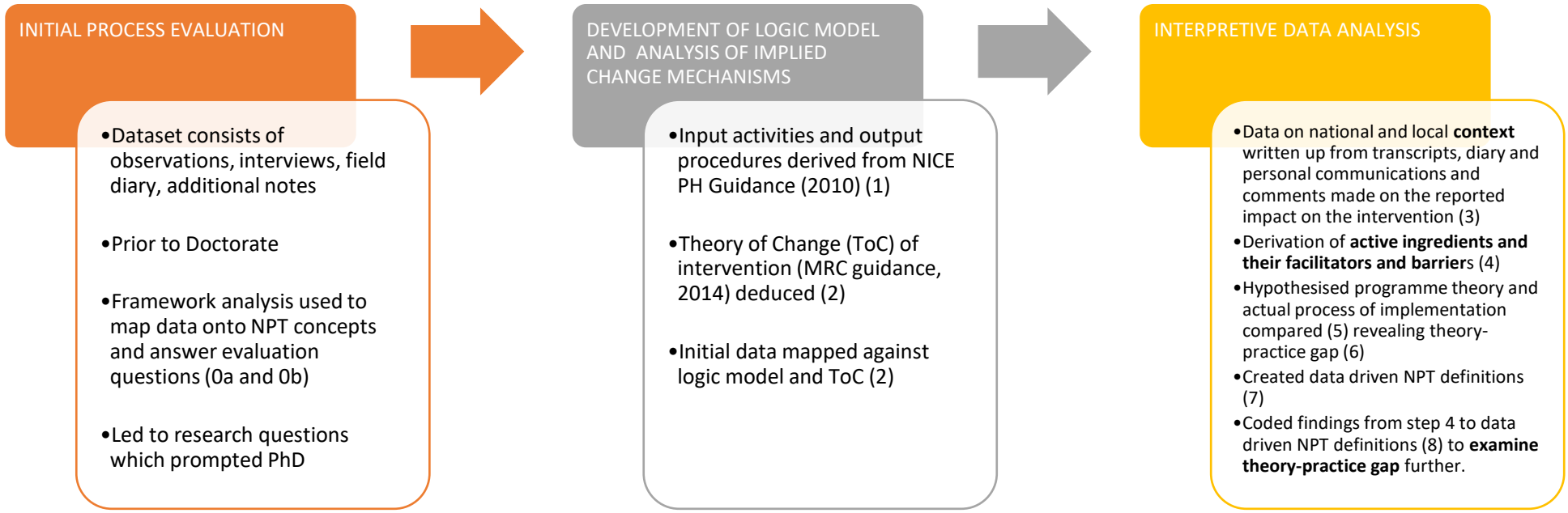
The analytical process in this thesis is relatively complex. For this reason, I will start with a diagrammatic representation of the steps in the process, as found in Figure 5-1.

The steps in the process are summarised as follows:

Primary analysis
Steps 0a and 0b

Secondary analysis
Step 1 - derivation of inputs and outputs from NICE PH Guidance (2010)
Step 2 - hypothesised ToC deduced from literature
Step 3 - description of contexts from data
Step 4 - derivation of active ingredients, facilitators and barriers from data
Step 5 - comparison of hypothesised and data-derived ToC
Step 6 - identification of theory-practice gap
Step 7 - creation of data-derived NPT definitions
Step 8 - application of NPT definitions to theory-practice gap

Figure 5-1: Steps in analysis



Primary data analysis

Observational data

My observation notes were either paper-based or electronic. Initially, in Step 0a, I coded them line by line according to NPT constructs. Key themes within the coding categories were named and the essence of the code explained. I noted adherence to the aims of the training sessions. In addition, I used the observational data to identify how babyClear© training differed from standard stop smoking training, as referred to by participants. Comments arising from analysis of the observations on the value of the training and its influence on the delivery of the intervention can be found in 5.4.

Interviews

I continued Step 0a by conducting an initial thematic analysis of the dataset prior to starting the doctorate. NVivo 10 software (QSR International) was used to manage the data analysis. I deductively derived topics and subtopics from issues within the interview schedules and coded them to the NPT core constructs. Definitions of codes were derived from May & Finch (2009) and other papers using NPT (Gallacher *et al.*, 2011; Finch *et al.*, 2012; Mair *et al.*, 2012). I coded and defined frequently occurring items (Ritchie, Spencer and O'Connor, 2003). Coding was checked by a second and third researcher (Professor Shucksmith and Professor Hamilton), then I sorted them into themes alongside relevant data extracts (Ritchie, Spencer and O'Connor, 2003; Braun and Clarke, 2006). I carried out interpretation of the themes by constructing a further 'framework' i.e. networks of relationship within each theme (Miles and Huberman, 1994; Attride-Stirling, 2001). I ordered cases by looking at a specific variable of interest and examining it to establish links that illumined the process of normalisation (Miles and Huberman, 1994). I applied these methods systematically as I grappled with large quantities of data and moved them through several analytical steps. This created a transparent, audit trail allowing others to check and/or follow the choices and decisions which led to the final findings. I used observation data to triangulate interview data; discrepancies were followed up during interviews. Data from all interview sources and observation sessions were examined for consistency.

The findings from the initial analysis were taken back to the service user reference panel to gain a patient/public perspective on them. They were presented in a way that was accessible and interesting to panel members. Members agreed with the overall findings presented to them; their comments are summarised below:

- They changed their minds about the use of shock tactics, as they now felt it set the ball rolling for some pregnant smokers

- They felt that the RPT could “give people a kick”, and that it was a kick that they needed
- They felt babyClear© made pregnant smokers more aware of what they could be facing as a result of smoking
- They believed you really do need to know all the facts about stopping smoking to make a decision
- They thought the SS message was something that staff needed to revisit and bring up gradually over time to keep it to the forefront when interacting with pregnant women, and that they should reinforce the message each time they saw a pregnant smoker.

I conducted a second thematic analysis of the dataset (Step 0b), using the methods outlined above, identifying and exploring the factors which helped or hindered the implementation of the babyClear© approach (Miles and Huberman, 1994). Five cross-cutting themes across the NPT concepts were found inductively. I wrote up these findings from Steps 0a and 0b in the report to SPHR (2016) and in Jones *et al*. (*QuitManager*).

Secondary data analysis

Subsequently, for the thesis, I conducted a secondary analysis on the same data. I started by developing a logic model and explicating the hypothetical mechanisms the intervention would use to create changed behaviour. Then proceeded with the interpretative analysis, to understand what happened during implementation, from the data. In this analytical process, I began by using software to manage and theme the data, alongside continuing to read through it, and the wider literature around methods, related topics and recent publications. I also used mapping and drawing to try out different ideas, to compare and reflect, as part of seeking out the bigger picture before focusing down on the minutiae. Sometimes tabulations were drawn from the data, collecting it in new ways and creating different structures. Returning to the software to group and categorise the data under different themes during a continuous re-working and re-thinking of the analysis. This involved various peregrinations, investigating some cul-de-sacs and many re-iterations until the findings emerged, as recorded here in the final narrative (Appendix 11.5.1).

Figure 5-1, Steps in analysis, with the corresponding coding plan (see Table 5-4), explains the process that was identified to answer the research questions. Each numbered step represents a block of work. NICE PH Guidance (2010) and MRC guidance (Moore *et al.*,

2014), a logic model and experimentally-derived mechanisms were the empirical elements of the analysis, in contrast, the research questions, data-driven coding, comparison of mechanisms and critical analysis used an interpretive perspective.

Table 5-4: Coding plan for analysis

Coding plan	
For the process evaluation	
0a	Whole dataset: Coded to NPT concepts and sub concepts
0b	Whole dataset: Key factors for implementation – used for SPHR report (2016) and Jones *et al*. (2019)
For the doctoral study	
1	Whole dataset: Coded to logic model and derived inputs and outputs from NICE PH Guidance
2	Hypothesised mechanisms of impact derived from the literature
3	Data on national and local context written up from transcripts, diary and personal communications and comments made on the reported impact on the intervention
4	Whole dataset: from step 1 derived active ingredients, barriers and facilitators via thematic analysis of data in each code and summarised for thesis
5	Comparison of hypothesised mechanisms and actual findings
6	Identified theory-practice gap
7	NPT concept definitions (derived from the data)
8	Applied definitions to the active ingredients, barriers and facilitators of the intervention activities and procedures to explore the usefulness of NPT in understanding the theory-practice gap

Findings from Steps 1-8 allowed for comment on the utility of NPT regarding feasibility, sustainability, transferability, fidelity, knowledge translation and theory into practice. Also, they allowed for comment on the strengths and limitations of NPT, in relation to the research questions, to be examined.

Using rigorous methods, as described above, and checking the initial process evaluation findings with a patient/public panel increased the credibility of the findings. However, even after conducting a further secondary analysis, it is important to accept it remains incomplete, not least because it is shaped by the context of academic examination (Pryke, 2003). By acknowledging that there will still be holes in the interpretation, and understanding it as, but

"a momentary pause in an endless flow" of thought and revelation, gives it a realism which it might otherwise lack (Benjamin, 1979, p131). The culmination of this analytical process is presented in Part 3; wherein the data are interrogated to meet the study aim and answer the research questions. The re-contextualisation and re-examination using the lens of NPT form the basis of Part 4, for discussing the findings and drawing out the conclusions and recommendations.

5.4 Primary analysis of the observational data

Training sessions were observed to have benefited the implementation and delivery of the intervention in a number of ways, but it was also devalued through questioning of appropriateness of the intervention, specifically around workability and fidelity in local contexts.

5.4.1 Inferred benefits from the training

Making sense of and engaging with babyClear©

A key benefit of the training was the core information that was taught. As outlined in 5.3.1, there were four types of training session and the teaching was moulded around the needs of each group. In-depth SS advisor training was most appreciated by midwives who were becoming new advisors or those developing their roles e.g. pharmacists, but less by experienced SSS staff, who found much of it already familiar. Similarly, the RPT training was highly valued by the midwives who would deliver this new tool. Reflecting on the value of the training one RPT midwife said:

> *… it is like anything new, and it is like domestic violence, asking those questions. Initially it is hard. You are prying and it is a sensitive subject, but when you get used to using the right phrases, and [babyClear© lead trainer] talked about crib cards, and we made some sheets with suggestions for opening introductions and the words to use, and once you have said them so many times it is easier*.

Interview, RPT Midwife, Trust C, 6th May 2014

One SSS manager, when asked about frequency of CO monitoring said:

> *Definitely, definitely, more frequently. I mean the training … gave it another boost, and it was kind of obviously linked to a regional initiative. So, it was given publicity and kind of status, yeah.*

Interview, Trust C, 30th June 2014

Yet this participant still questioned the coherence of babyClear©:

> *I mean I have no doubts whatsoever that the CO monitoring at every opportunity is worthwhile, but whether this huge concentration of staff and*

money on these very hard to reach and resistant women is worthwhile is still a question mark for me.

Ensuring that the intervention is coherent to HCPs is an important tenet of NPT, so that they would readily engage with the process. This was an aim of the training; however, some HCPs were left with some doubts.

Differentiation

The training differentiated between previous practice and the babyClear© pathway. Following a series of 2-hour sessions for community midwives, I noted down the differences in the message they would be expected to communicate, from the trainees' perspective, as follows:

Routinisation of CO monitoring

Smoking has been normalised in our culture both in hospitals and homes and we need to recognise it as abnormal, like the use of any other harmful product.
CO monitoring becomes the same as monitoring any other level that is an indication of the potential to harm e.g. protein or glucose in urine.
Aim to identify all and any sources of CO in pregnant women.

Opt-out referral

Instead of using opt-in referral to the SSS, it will become an opt-out. Examples of phrases to be used: "Due to my concern at this level of CO in your blood and the baby's blood I am going to refer you to the SSS".
"We will contact you by all these means, is that ok with you?"
Not giving a direct choice although always have the right to refuse.
Document and sign any refusal by a woman to being referred.
Your duty of care is to refer; documentation provides legal cover for you; so document that the woman has received and understood the risk and made a fully informed choice.

Change of language

'Test' becomes 'screen'.
Use 'CO monitoring', not "do you smoke?"
'Low birth weight' becomes 'underdeveloped baby', needs the extra weight to be fit and healthy.

Passive smoking becomes second-hand smoke, implies it is within your control, unlike passive smoking, which suggests you cannot do anything about it.

Impart skills to challenge without damaging the relationship between HCP and patient
Medicalise the discourse e.g. routine screen, everyone is screened, if levels are high refer to a specialist.
Focus on all causes of CO in their body, not just smoking.
Use the monitor reading as an opportunity to discuss risk.
Focus on your duty of care.
Use words like 'worry', 'concern', phrase the message to encourage compliance.

Reducing acceptable level of CO
Safety level reduced to 4ppm. Was 10 ppm (NICE 2010) and 6 ppm (locally).
Rationale is that this way will catch all at risk from CO and allow for discussion of the cause.

Introducing a more sensitive CO monitor
Never reads 0 as previous ones did, as it registers CO in air.
Portray as many sources of CO as possible, explain they all harm their baby.
Be aware this may lead to concern at readings which are acceptable, the monitor alarms at a lower reading.

Changing design of monitor in use
Monitor no longer requires calibrating.
Must not use alcohol-based cleaning agents, change from infection control recommendations, use soap and water only once wipes it is supplied with run out.

I also noted some differences in process introduced with babyClear©:
Taking every pregnant woman's CO level
Completion of details for multiple forms of communication on SSS referral form (to increase options for follow up)
Enter HCPs' own code onto each referral form; now will be able to monitor activity of each staff member.

Role of SSS to decide the source of a raised CO level; midwives to identify and refer then leave to specialists. Follow up referral as necessary.

Referral time now faster; maternity staff to send to SSS within 48 hours, SSS to contact woman within 24 hours.
Introduction of the risk perception tool (entirely new).

These differences were picked up in all training session types. They related to three issues; firstly, embedding NICE guidance (2010) where it was not yet normalised; secondly, altering the discourse between HCPs and pregnant smokers and thirdly practical/system changes.

They also clarified and emphasised the mechanisms for changing pregnant smokers' behaviour. During a 1-day advisor session, held on 25/9/13, I identified these from the session as:
Empowerment
Bring smokers to the point where they themselves feel ready to quit
Overcome the barriers to quitting
Explode untrue beliefs
Clarify misunderstandings
Support to change
Build self-confidence
Build self-control
Increase self-belief, that they can do it
See stop smoking as part of antenatal care, like a treatment for any other condition
Inform the smokers of the 'facts' as understood by the medical and research communities.

Exploring workability

Training provided a basis for exploring how babyClear© would work, individually or in teams, and in practice. This is an initiative that seeks to standardise a protocol, based on embedding NICE guidance (2010), so each pregnant woman receives the same intervention, tailored to her circumstances. The trainer was confident in explaining how it could be implemented.

Increased coherence

Midwives spoke of how the training had increased the coherence of the intervention for them, but it did evoke strong language from team members in response to this 'brutal' approach:

> *BabyClear© [training] made us realise how we use the softly, softly approach, but some girls do need it ramming in their face. It's brutal. In this*

trust it is those that we are targeting now. All the others, who respond to the softly, softly approach, are already in the system, being seen by the [care assistants].

Community team focus group, MCA 6, Trust C, 8th May 2014

Increased confidence and skill

After the RPT training midwives expressed concern that they were not fully ready to deliver the tool; however, this uncertainty left them once they started using their skills to deliver the tool:

Yeah, and amazingly, better than I thought. I was a bit worried about doing it [deliver the RPT], when I went on the training day, I was what, this really can't do this, but I'm actually enjoying it and the reception has been quite good. People have been, some have even thanked me, so it's been good.

Paired interview, RPT midwife 12, Trust F, 15th January 2015

Overcoming reservations

During the training period there were many reservations voiced about the RPT but generally these were not realised. There were also concerns expressed by community midwives regarding requiring extra time to conduct the CO monitoring, within an already packed consultation scenario. However, again these were not borne out:

Interviewer: So, is that more work for you then, if you're doing more referrals?

PT: It is, it is but it just becomes part of you.

Interviewer: You don't feel it's a heavy burden or an extra?

PT: No, I think when they bring new things in you think 'how on earth am I going to do this?' but you just do it as part, it becomes part of your daily work and for the sake of a couple of minutes to fill a form in and a couple of minutes to fax it, and the potential benefits to that really, it's got to be worth it, especially 5 minutes in your time.

Interview, Community Midwife 6, Trust A, 27th February 2014

Increased engagement

Starting with the training, then seeing it in practice, midwives were persuaded that the RPT was effective in some circumstances:

… in the risk clinics that public health midwives run, I think that's very powerful and I think if we could do that for all women, it would be ideal, but obviously we haven't got the time to do it for all women, but I think, I think we have had some really successes with that risk perception clinic, because I think, even though you're testing them for the, you know, the

carbon monoxide, I still think some of them, just think, oh well, you know, I'll still smoke, it doesn't matter, where that visual of the risk perception is really powerful, I think.

Interview, Senior Manager 8, Trust B, 15th September 2014

5.4.2 Training devalued

Time restrictions

There was a constant pressure to run the 2-hour community midwives' sessions to time due to midwives/MCAs work commitments. This was demonstrated by some trainees arriving late and others leaving promptly/early. This rather hurried approach meant there was no extended discussion time and only vital information could be included. The 2-day advisor training was compressed into a 1-day session for the same reason. On arrival, there was a general perception that much, if not all, of the information was familiar to them already. Although staff did talk afterwards about learning new information, especially relating to the RPT.

Perceived lack of workability and fit

The content, coherence and engagement by trainees with the training sessions were challenged by the perceived lack of workability and fit of the intervention in local contexts. As time went by, the training sessions, while trying to remain focused on their stated aims and objectives, also elicited the differences between the context in which the intervention was developed and the variety of contexts that existed across the implementing Trusts. The information provided during training did not fit with some of the existing models e.g. it was designed for midwives who refer to a separate SSS, not for in-house SSS, and where there is an RPT trained midwife in all scan clinics attended by pregnant smokers (see 7.3, 7.4).

[the trainers] wanted it [RPT] to be led by the nurse [midwife] in the nurse [maternity] setting, because they show them some quite difficult pictures about babies and placentas and stuff. So, they wanted that done there, and they refer into us afterwards once they've decided they will quit.

Paired interview, Pharmacist 1 and Pharmacy Technician 1, 6th November 2014

… the thing that was really difficult and the thing that the trusts had a nightmare getting their heads around was we wanted to provide the Stop Smoking intervention onsite when they were doing the scanning clinics. And the biggest difficulty was, they run scanning clinics every day and actually persuading the Head of Midwifery to put the smoker, the pregnant smokers into one clinic was probably the biggest hurdle that we got over, because that allowed us then to have the Smoking Service onsite.

Local Authority SSS managers 1 & 2, SSS J, 12th December 2014

Support from SSS was not always available:

> *We're working with the risk perception tool. You're bringing a woman in, you're telling them that there's a real issue with the level of CO in their baby, we're giving them products to go out, but then there's no support mechanism being able to be offered outside of that. And it worries me a little bit ethically, that it's a little bit cruel, that we're frightening women saying, you know, you really need to stop smoking, look at the health risks associated with this, but then there's nobody at the other end picking it up and giving them the support.*

Interview, Senior Manager 1, Trust A, 5th August 2014

This unexpected challenge was heightened when the trainers emphasised that babyClear© had to be delivered according to the original protocol. Midwifery staff were keen to maintain the differences within their areas, where they believed it was working well, and expressed doubt about how it could be implemented without adaptation to their context. Pharmacy staff, in areas using pharmacies to provide the service, were keen to implement the intervention but frustrated by their lack of clients, an indication of gaps in the system. This concern over workability and fit created dissonance for the trainees.

5.4.3 Working towards fidelity

Each location had different pre-existing systems (see 7.4), so there was no standard system, the detail of the protocol was still in the process of being agreed, systems were still being devised and then tweaked while training was ongoing, in an attempt to implement with fidelity. Questions continued as to the practical implications in the areas where the trainees worked. The detail of the process for each area often remained unclear. This resulted in contradictory information being voiced. This resulted from the training pushing ahead without full information and before service process negotiations were completed.

Interview data shows that system changes were required to enable the implementation. This was especially clear regarding the RPT, where it took many months to become embedded:

> *… every Wednesday [the clinic] should be full of smokers - but we have had difficulties with midwives … using the old forms ... I would say we're probably only, you know, reaching probably half the women that we should be, you know, not even half maybe.*

Interview, PH midwife 1, Trust B, 21st March 2014

Changes to referral forms were still being made, the timing of CO checks was also being modified, as seen in this exchange between an RPT midwife and MCA:

Midwife: … We are looking at stopping the CO test when they have their bloods done immediately before the RPT because it blows lower then.

MCA: Oh, does it, why?

Midwife: Because they have emptied the bottom of their lungs, where the CO is, into the monitor already, then when they fill up again it is not so high. They may blow a 12 with you [in the blood test] then an 8 with me and the visual impact of the baby on the screen is less. At lower levels it will only be amber, not red or flashing red.

Community team focus group, Trust C, 8th May 2014

Alterations were also made to the location within the clinic of the stop smoking follow up relative to the scanning room:

They've moved the room as well where the ladies get their bloods taken, so we're all in the room next door to where they have the risk perception so now the healthcare assistant that takes the blood is now opposite the room where the risk perception is, so basically, they come out of one room straight into another then come and see us, so …

Focus group, PH nurse 2, SSS J, 8th November 2014

These threats to workability, identified in the primary analysis of the observation of training, became more apparent over time. Some Trusts found it easier to overcome than others:

… the logistics of putting a new service in with no extra staff or hours was always going to be difficult and so we've had to be creative to be able to manage it and we have.

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

The trainer responded to questions about feasibility and fidelity in later training sessions by finding out the details, promising to take them back, find out what was happening, and feeding back to the trainees. She put the onus on the trainees to contact her for feedback (the data does not reveal if they did so). The trainers continued to insist that the intervention must comply with the original protocol, even as it was becoming more apparent that this was not easily workable in all contexts.

Although the training sessions were internally evaluated, there was no overall plan by the trainers or the Trusts to review the value of the training or its influence on fidelity or sustainability of the intervention. The workability and fit of the training timetable was assumed which resulted in missed opportunities e.g. time limitations meant the RPT was barely mentioned in community midwives' sessions, yet they will be picking up with patients

after it has been delivered; it could have been a forum to discuss ways to integrate the RPT into present systems and/or identify someone interested in delivering it. Assumptions were also made about the implementation, so no formal route for feedback of warning signs were available to alert the service decision-makers of any challenges elicited by the training.

5.5 Chapter summary

Primary evaluation of the implementation of the intervention was carried out prior to the doctoral study. Analysis of the observation data recognised that while training was valued it also showed early signs of threats to workability and fit of babyClear©. The aims of the thesis are different from those of the process evaluation and focus on the secondary analysis; however, it is important that the data used in the thesis was produced ethically and in a rigorous way. This chapter has set out the broad parameters of the operationalisation component of the research process, including evaluation study design and the specifics of the collection of the data which underwent primary and then secondary analysis.

PART 3

This section is divided into three chapters, which focus on the analysis and findings (Exploring the Programme Logic, Analysis and Findings 1 & 2). The pre-implementation and pre-planned intervention phases have been described in Chapter 1, and the method used in the initial process evaluation is set out in Chapter 5, as is the method of secondary analysis. I carried out all secondary analytical work specifically for the thesis, as outlined previously in Figure 5-1: Steps in analysis. A diagram of the analytical decision process can be found in Appendix 11.5.1. The RQs encapsulate the questions that arise from the literature around complex interventions in public health and how NPT might be used to interrogate the study data.

Research questions (RQs)

1 To what extent does the NPT framework successfully allow:
a) identification and
b) elaboration
of the process of normalisation of a complex intervention?

2 To what extent does the NPT framework assist in understanding:
a) feasibility and
b) fidelity
whilst allowing interventions to be adapted to the needs of the complex systems in which they operate?

3 To what extent does the NPT framework assist in understanding:
a) sustainability and
b) transferability when scaling up to population level?

From the literature it has been established that:

1. The examination of factors overlooked by experimental methods is fundamental to understanding how, why and to what extent complex public health implementations succeed or fail (see Chapter 2).

2. NPT has been posited as a mid-range theory to help understand this process of implementing complex interventions and to reduce the theory-practice gap (see Chapter 3).

Bearing this in mind, in Chapter 6, I explore the programme logic underlying the intervention. I begin with a description of usual practice and the standard stop smoking in pregnancy service (SSPS) delivery model for which the intervention was designed. Then I present a logic model, extrapolated from NICE PH Guidance (2010), which sets out the Theory of Change (ToC) of the intervention. I also explain the evidence-base for each mechanism. This logic model forms the basis for analysing the delivery and impact of the mechanisms.

In Chapter 7, I relate the story of the analytical journey. I describe the various contexts into which the intervention was introduced, report how each mechanism was applied and the result, from the data. By coding the data to the inputs and outputs of the logic model, this thematic analysis elicited the active ingredients, barriers and facilitators for the mechanisms.

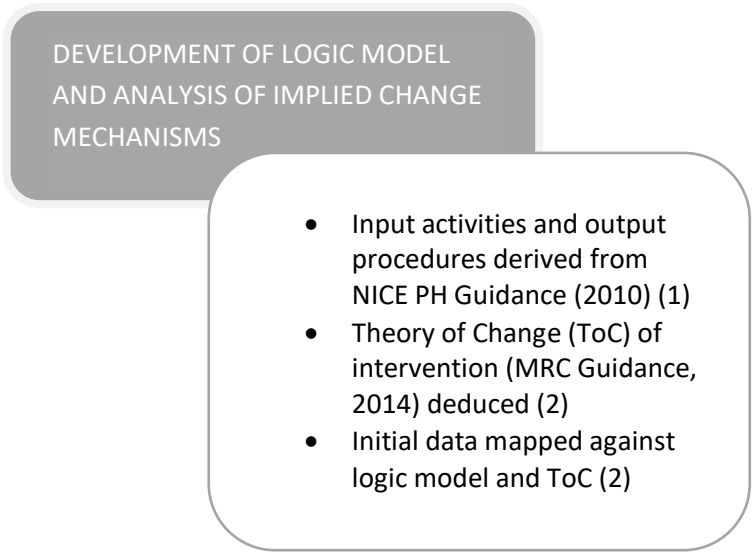
In Chapter 8, I explain how NPT brings to light the factors that impact on the outcomes, but which are neglected in trial methodology; then I move towards examining the role of these factors during the implementation. To accomplish this, I take the study data and use it to define the NPT concepts, which I apply to the findings from Chapter 7. I use the comparison between the hypothesised and reported mechanisms to explore 'congruence, or not, between predicted and observed phenomena' (May *et al.*, 2007a, p2 of 7). This echoed the pre/post design used by some other authors when applying NPT (Gask *et al.*, 2010; Kennedy, 2010; Green *et al.*, 2015). This was necessary firstly, to understand the extent to which the NPT framework successfully allowed the elaboration of the process of normalisation (RQ 1) and, secondly, to examine the theory-practice gap (RQ 2&3).

Chapter 6 EXPLORING THE PROGRAMME LOGIC

6.1 Introduction

This first chapter of the analysis and findings section explains the derivation of the source data and explores the analysis undertaken to elucidate the (otherwise hidden) programme logic behind babyClear© (Steps 1 & 2) as summarised in Figure 6-1.

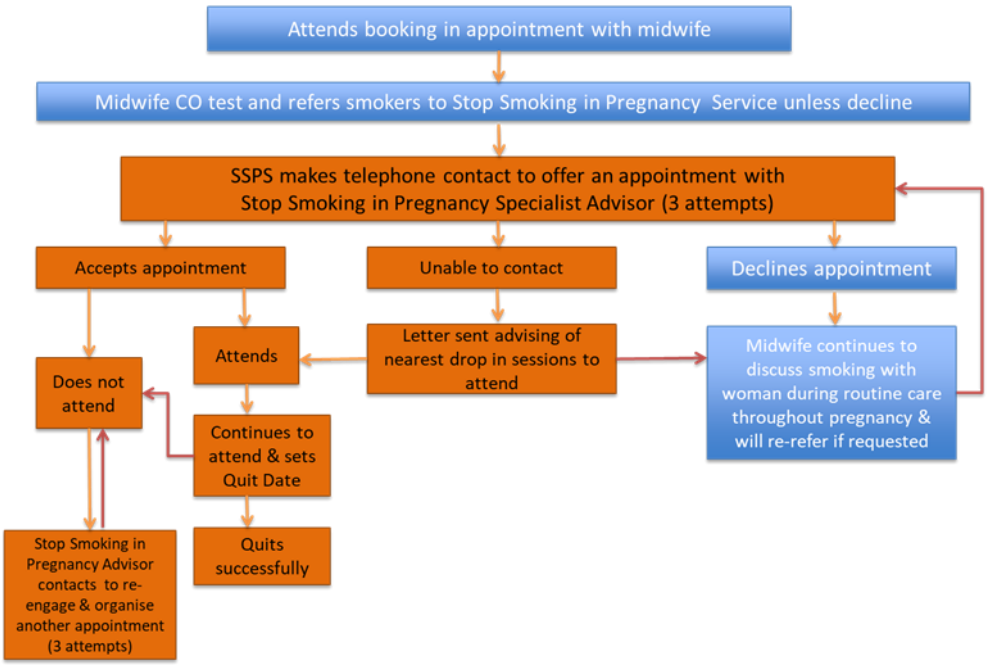
Figure 6-1: Stage in analysis – development of logic model and analysis of implied change mechanisms



6.2 Standard Stop Smoking Service delivery model

From my data - in particular, from interviews with those who trained the staff - I discovered that the intervention example was designed with certain assumptions in mind regarding a standard SSPS service delivery model (SDM) (Figure 6-2). I found that this standard model was based on NICE PH Guidance (2010) and pragmatically derived from the area where the intervention designers worked. It was expected, by those who trained the staff, that the intervention would be introduced into systems operating to the same standard SSPS SDM, as in Figure 6-2. However, my data started to challenge this assumption.

Figure 6-2: Standard SSPS service delivery model



Key characteristics:

- First contact at booking-in appointment
- Specialist pregnancy stop smoking advisor who is a midwife; available in hospital antenatal clinics for follow up and able to deliver the RPT
- Discrete dating scan sessions suitable to be followed by RPT
- No Maternity Care Assistants.

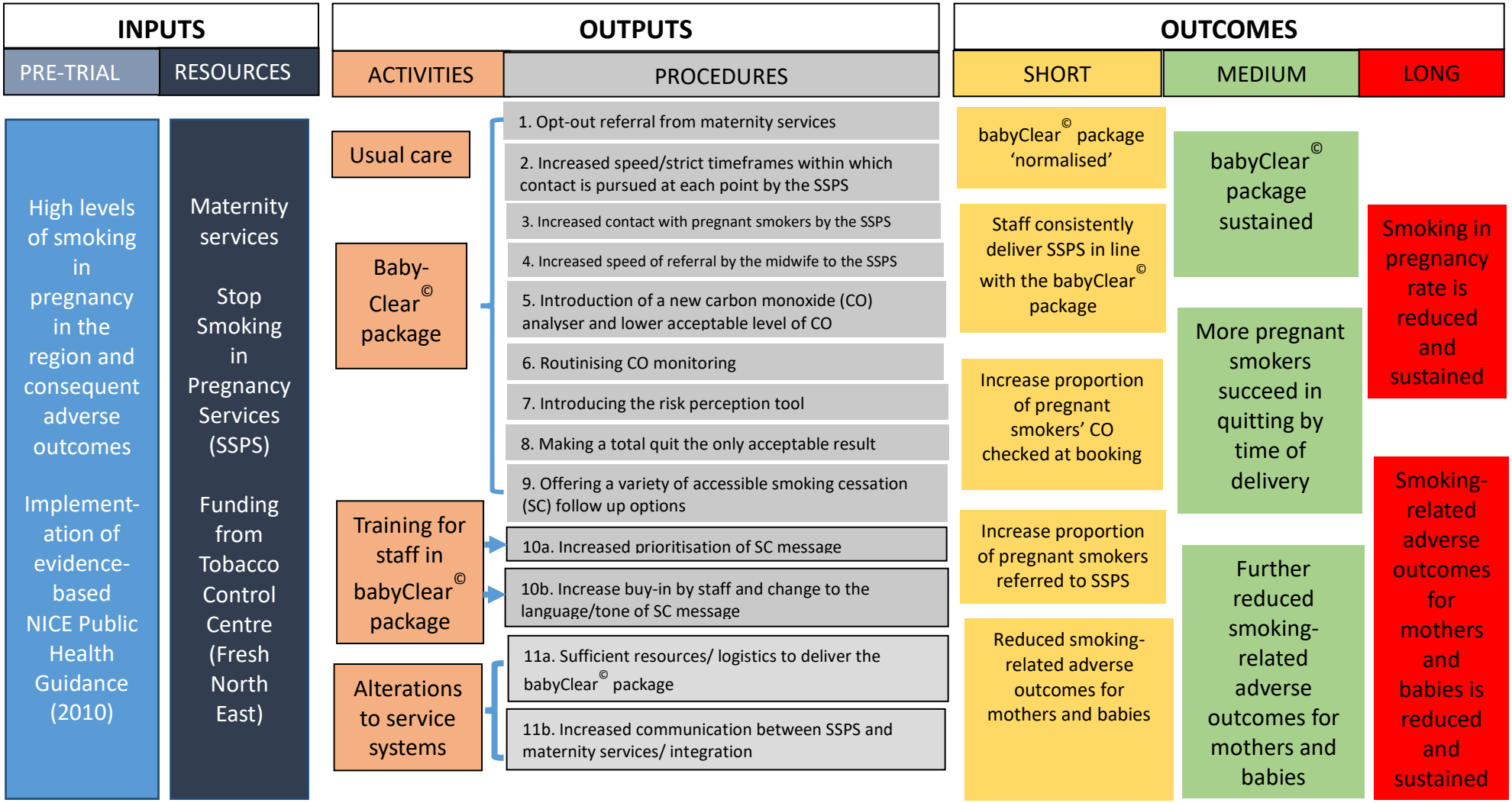
6.3 Logic Model

Logic models are used to describe the expected ToC; which is an important first step when introducing an intervention (see 2.5.1). However, it quickly became evident in undertaking the initial process evaluation that no logic model existed to encapsulate the programme theory behind the intervention example. In interviews, the intervention was often described as ‘pragmatic’ and based on professional experience, as well as being largely guided by trial evidence from NICE publications. It appeared that the intervention prescribed WHAT should be done without considering WHY it was to be done or what the intended outcomes would be from such actions. It thus became clear that a first step in the secondary analysis should be the retrospective derivation of a logic model to determine the programme theory. This echoes the assertion of Rose (1982), that the research process must be ‘logically consistent’ (p20).

I therefore developed a retrospective logic model for babyClear© (Steps 1 & 2 in Figure 6-1), as set out in Figure 6-3. It was developed from what was known about the origins of the study, NICE PH Guidance (2010), the babyClear© package and the evaluation proposal. This was supplemented by interview data, personal communications within the evaluation team and reflections in a field diary. Face validity of this logic model was checked with those who had developed the babyClear© intervention (Fendall, 2018; Wareing, 2018a).

Insufficient evidence was available about the operational context for this specific intervention; although work in the field could have been drawn on to hypothesise key contextual influences. It is often the case that the *context* required for the optimum operation of the logic model is not explicitly expressed or discussed (Craig and Campbell, 2015).

Figure 6-3: Logic model of the intervention



6.4 Mechanisms of impact

The development of the logic model identified the procedures and activities that were expected to realise the outputs, outcomes and impact. Thus, the logic model would act as a vehicle for knowledge translation. For the thesis, I tabulated each activity within the intervention package and the hypothesised link or mechanism of impact (see Table 6-1). I have also provided the evidence for each mechanism, where available. Hypothesised mechanisms are based on information gained through scoping for the evaluation, data collection and the literature (NICE, 2010; NPT papers; Fendall *et al.*, 2012). See Chapter 7 for detailed evidence.

Table 6-1: Hypothesised mechanisms of impact

Procedures	**Question – what needs to be linked?**	**Hypothesised Transition Link or Mechanism**
ACTIVITY: babyClear© package of measures		
1	How does opt-out referral from maternity services increase quit rates?	Creates a barrier to the pregnant woman opting-out and a nudge/incentive towards opting in. Pregnant women who smoke are less likely to accept responsibility for the effects of their smoking or believe that they can quit, so nudging them towards greater support is more likely to improve outcomes. This needs to be complemented by an empowering discourse from the HCPs.
2	How do increased speed/strict timeframes within which contact is pursued at each point by the SSPS increase quit rates?	Catching the teachable moment in early pregnancy, being contacted and treated in ways that increase rapport and relationship through a protocol of frequent contacts is most effective.
3	How does increased contact with pregnant smokers by the SSPS increase quit rates?	The more times pregnant smokers are reminded and have to reject the advice the more likely that, on one occasion, they will accept it.

Table 6-2: Hypothesised mechanisms of impact CONTD .1

Procedures	Question – what needs to be linked?	Hypothesised Transition Link or Mechanism
4	How does increased speed of referral by the midwife to the SSPS increase quit rates?	The sooner the pregnant smokers are faced with the reality of the effect of their smoking, the more likely they will be in a teachable moment, in the early stages of pregnancy, and also the increased number of interventions they will be exposed to. More smokers will then have the support of services to quit, which is known to improve outcomes.
5	How does the introduction of a new CO analyser and lower acceptable level of CO increase quit rates?	The analyser is very visual, literally alarming, includes a read out for the baby as well as the mother and plays on her concern for her baby. By reducing the cut-off level more women and more smokers will fall within the criteria for referral. More will then have the support of services to quit, which is known to improve outcomes.
6	How does routinising CO monitoring increase quit rates?	If it is routine it becomes the expected norm by staff and pregnant women. Pregnant women come to expect it and may use it as a motivator for quitting. More smokers will fall within the criteria for referral. More will then be contacted and have the option of support of services to quit, which is known to improve outcomes.
7	How does introducing the RPT increase quit rates?	Coming from a position of care and concern, yet presenting the risk visually and strongly, in ways that force pregnant smokers to face what they are doing to their unborn baby, gives some of them the impetus they need to change.

Table 6-3: Hypothesised mechanisms of impact CONTD. 2.

Procedures	Question – what needs to be linked?	Hypothesised Transition Link or Mechanism
8	How does making a total quit the only acceptable alternative increase quit rates?	Even an occasional puff makes it impossible to break the body's addiction to nicotine, so the smoker will go back to smoking, even if they have cut down, and, given time, it is also likely to increase again.
9	How does offering a variety of accessible SS follow up options increase quit rates?	Reducing barriers to accessing support will maximise the opportunities for pregnant smokers to be supported to quit. Increasing the options reduces the barriers to not engaging. It genuinely allows more women to access services conveniently and in ways that fit into their lives. Improving access to support will improve outcomes, as we know that pregnant smokers are more likely to quit with service support than without.
		ACTIVITY: Training
10	How does the training increase quit rates?	Through prioritisation, routinisation, new discourse and boosting buy-in by staff.
	a) How does increased prioritisation of the SS message increase quit rates?	By prioritising it, it will be at the forefront of the mind of HCPs and pregnant women; opportunities to mention stop smoking messages, refer women to services and face them with accepting or rejecting the offer, will be increased. Mothers less able to continue to smoke unchallenged. Frequently impresses upon the mother who smokes the importance of quitting. More women will be signposted more often to take up support from services to quit, which is known to improve outcomes. HCPs less able to condone / ignore smoking of mothers.

Table 6-4: Hypothesised mechanisms of impact CONTD. 3

Procedures	Question – what needs to be linked?	Hypothesised Transition Link or Mechanism
10	b) How does changing the language/tone of the SS message improve outcomes?	Goes beyond non-judgemental to show real care and concern for the mother and join with her to bring about her greatest wish, a healthy baby. Appeals at an emotional rather than an intellectual level. Makes the mother feel genuinely cared for, that someone sees her as important enough to spend time with her and show her how she can achieve a quit.
	c) How does introducing changes to the language of the SS message, from midwives/MCAs/administration staff/SS advisors, increase quit rates?	Not only does the language of care and concern take non-judgementalism another step forward, it is more person-centred and empowering and puts the HCP on the side of the woman; it treats her as someone precious and so reduces the gap between them; it also strengthens her to sustain changed behaviour.
	d) How does increasing buy-in to the intervention by HCPs improve outcomes?	The message will be communicated more effectively and ensure actions are readily taken to embed and normalise the intervention, including overcoming any hindrances to its adoption.
ACTIVITY: alter service systems		
11	How does changing the systems to accommodate the babyClear© package increase quit rates?	Various elements have been in place in part before, but a systematic approach maximises the effect. Introducing the various elements of the babyClear© package together allows for synergy. No one element alone will be as effective, although they are all securely evidence-based. Maintains greater consistency across care settings for pregnant smokers.

Table 6-5: Hypothesised mechanisms of impact CONTD. 4

Procedures	Question – what needs to be linked?	Hypothesised Transition Link or Mechanism
11		Creates a seamless pathway for the pregnant smoker, with both services working together, requiring them to communicate regularly. Feedback loops are an important tool for continuity of care, reviewing progress for patients and service delivery and creating a sustainable system.
	a) How does providing sufficient resources to deliver the babyClear© package increase quit rates?	Resources are essential to the implementation process. Without appropriate and adequate resources, the pathway cannot be enacted. The sooner and more efficiently resources are brought to bear on the situation the easier and smoother it will be to implement and produce the outcomes.
	b) How does increased communication / integration between SSPS and maternity services increase quit rates?	By establishing robust feedback loops - from the woman's perspective, at each consultation, the HCP (doctor, nurse, midwife, stop smoking advisor) knows what the services have offered, if she has taken it up, her latest smoking status and her attempts to quit (or not) - from the HCPs perspective, they are fully informed as above The results of this - women are then less able to play the system; pull the wool over the eyes of HCPs and know they will be found out if they do - women try to play the system less and so have to face up to the consequences of continued smoking more - HCPs from both services are fully informed and better placed to support women e.g. the patient feels more important and secure if all the information about them is present, the HCP can tailor their advice confidently, therefore the outcomes will improve.

6.5 Conclusion

The key finding from this chapter is that to understand what NPT tells us about the process of implementation when scaling up complex interventions, all aspects of the intervention need to be made transparent, including the context. This chapter provides the basic understanding of the intended service delivery model, the intervention, its causal assumptions, mechanisms and outcomes required to critique NPT. A logic model was developed as part of the secondary analysis and is presented here to investigate the way the mechanisms were hypothesised to work to bring about the outcomes i.e. to translate the research knowledge into practice. The evidence on which the mechanisms sit has been well-rehearsed over the last two decades and more; however, it is proposed that the context has been largely overlooked. The information in this chapter will be used to inform the further findings chapters.

6.6 Chapter summary

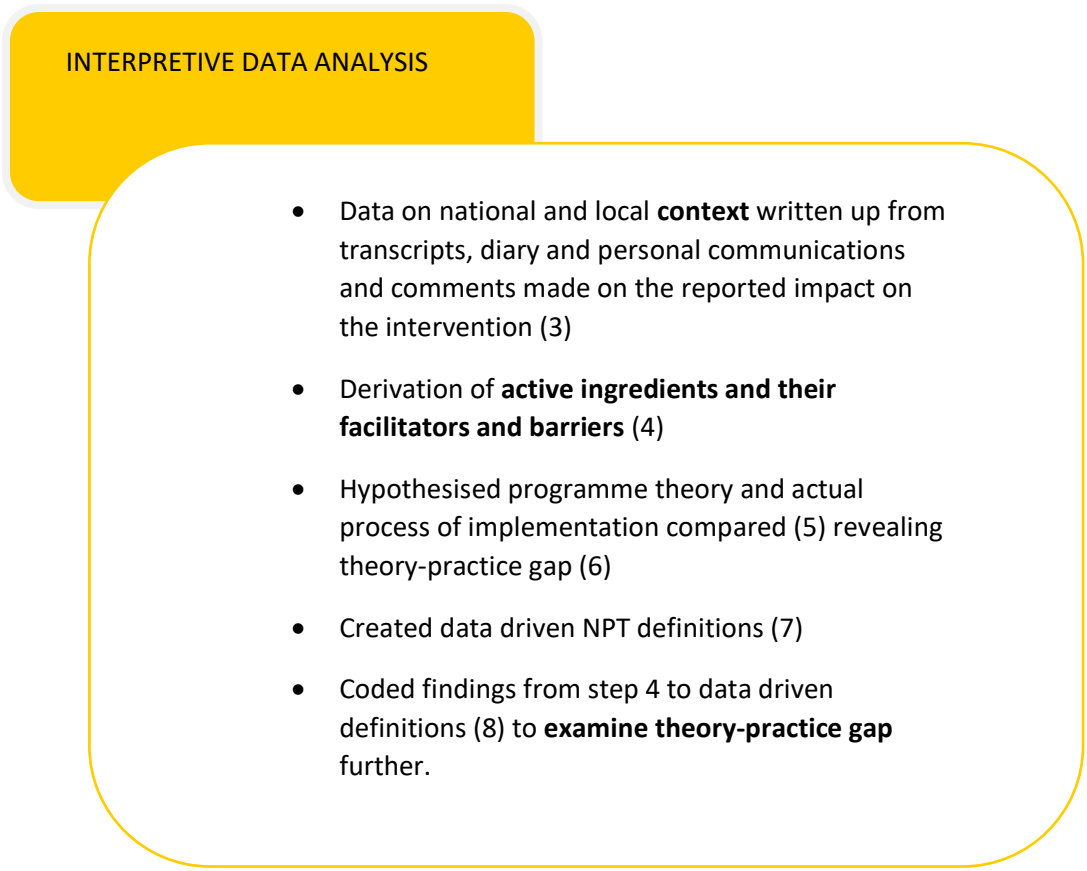
This chapter presents the first stage of the secondary analysis and findings. It describes the ToC of the intervention. This focuses on the programme logic i.e. mechanisms of delivery and change, by which the activities and procedures were expected to realise the outputs, outcomes and impact. The evidence for each mechanism is stated and begins the translation of knowledge from research to practice.

Chapter 7 ANALYSIS and FINDINGS 1

7.1 Introduction

This chapter forms the groundwork for answering the RQs. I present the contextual data followed by the hypothesised mechanisms of impact. By comparing these with the data from the intervention example it was possible to derive the active ingredients and their facilitators and barriers, as summarised in Figure 7-1.

Figure 7-1: Stage in analysis – interpretive data analysis



In this stage in the analysis I relate the story out of the field diary of the variety of contexts into which the standard intervention was implemented (Step 3) (see 7.2 – 7.5). I lay open the empirical assumptions of the package of measures through a rigorous exposition of the underlying hypotheses, anticipated active ingredients, barriers and facilitators and how they were operationalised during implementation (Step 4) (see 7.6). Specifically, I begin to identify and elaborate the process of normalisation, required to answer RQ 1 (Steps 5 & 6).

My first concern in this chapter is to understand the impact of the general environment and specific context on implementation of this intervention, which consisted of trials-based elements from NICE PH Guidance (2010) (see 6.4, 7.2 – 7.5). The importance of context as a variable when introducing complex interventions has already been noted (see Chapter 2). Details relating to environment and context are critical because they fundamentally impact on the implementation of the intervention, both logistically and through affecting the mechanisms by which impact is expected to happen (Moore *et al.*, 2014; Moores *et al.*, 2017; Craig *et al.*, 2019). Environment and context can either help or hinder progress and effectiveness (Moore *et al.*, 2014; Bauld *et al.*, 2017). Understanding what it is about them, that acts upon the delivery and impact mechanisms, is vital to identifying how to maximise the facilitators, reduce the hindrances and improve the outcomes (O'Cathain *et al.*, 2015).

My second concern in this chapter is to show how I explored the mechanisms of impact identified by trials evidence as compared with the actual mechanisms during implementation, arising from the data. This starts to answer RQ 2 by contemplating fidelity and feasibility.

Thirdly, through this journey of sensitisation using an NPT viewpoint, I want to show how I made explicit what was implicit from trials evidence. I will demonstrate how the main features - relating to normalisation - arising from this chapter, are relevant to the theory-practice gap.

Steps 3-6, outlined above, will provide the platform to compare the empirical evidence with the process evaluation findings using NPT (Step 8). Supplementary information for this chapter, in addition to the main dataset, has largely been recorded in the field diary, and is backed by reference to academic publications, government documents and public media.

7.2 National context

Please refer to Appendix 11.2.4 for additional information and references for this section.

7.2.1 Legislation, media and publications

There has been growing public and political support for quitting smoking in recent years - for example support for continuing the national smoking ban introduced in 2007; national, annual initiatives like Stoptober, No Smoking Day, and other stop smoking campaigns by national bodies like PHE and ASH. More specifically, 'Misbehaving mums-to-be', which promoted babyClear© as an effective intervention, was shown on national television in 2011. It was referred to during the training and was remembered by some of the staff participants who delivered the RPT (Pregnancy Specialist SS advisor 2, RPT trained midwife 12).

NICE published its public health guidance on stopping smoking in pregnancy in 2010 and updated it in 2013, however there were no major changes at this later point. Since its publication in 2010, the messages it carried have been supported by reports from other bodies, including the RCP and TAG (2010; 2018), RCOG (2014a) and Challenge Group (2013) (a consortium of maternity and stop smoking organisations). These include ASH, a campaigning organisation, which continues to lobby for effective support to quit and regularly disseminates SS information and research (ASH, N.d.).

Nevertheless, the RCM - the midwives' professional Trade Union - did not initially come out strongly in favour of CO monitoring to assist in quitting (O'Gorman, 2011), citing issues regarding increasing women's guilt, worries about making the midwife 'police' women's behaviour and potentially damaging their relationship with women by undermining trust. However, it has latterly become less equivocal and has signed up more wholeheartedly to NICE PH Guidance (2010) (Lowry, Scammell and Challenge Group, 2013; RCM, N.d.).

One further, significant change has been the introduction of electronic cigarettes onto the UK market. This has been a gradual process that has gained momentum since 2010. At the time of data collection for the study, e-cigarettes were only just becoming more widely available; it was too early for research with large cohorts of participants to be completed (Chamberlain *et al.*, 2013). SSPS advisors were unsure of their impact e.g. wondering if women would switch to e-cigarettes rather than quitting the habit altogether, or the advice they should give, bearing in mind the lack of research evidence and that clients were categorised as non-smokers if using e-cigarettes exclusively. This classification created a contradiction within the systems, in that if recent smokers were using e-cigarettes as a quitting tool, they were immediately disqualified from using the SSPS; however, it is known that a quit supported by SSPS is much more likely to be successful (NICE, 2010).

> *Interviewer: … the whole sort of national scene really … Do you have any thoughts on the way you see things going?*
> *Participant (PT) 105: I think our biggest thing at the moment is e-cigarettes and the number of women that come through (agreement round table) and say I am now using this, or I was thinking about using this,*
> *PT 107: Yes, I've heard that a lot.*
> *PT 105: And that's probably our biggest, I don't want to say, yeah, challenge.*
> *PT 106: Yeah, it's something we need to get on-board with on a national level and this and then filtering down to individual Stop Smoking Services, they're our biggest, you know, the amount of people using these cigarettes has increased massively and not just pregnant women. We are seeing people come through our door all the time*

who either have been using e-cigarettes, are using them or are thinking about using them.
Interviewer: Are they using them as a quit mechanism?
PT106 and 105: Yeah.
PT105: The majority yeah. But because they're using them it stops them from receiving the support. Well they think they don't need the support because they haven't got this, and what we're trying to say is, well actually support is probably the biggest, you know, to get you quit. We need to engage them into the service.

SSS staff, Group interview, 31st January 2014

Interviewer: So last question is about the smoking cessation agenda … How do you see that going over the next say 5-10 years?
PT: … I mean none of us foresaw the rise of electronic cigarettes.
Interviewer: Absolutely!
PT: Which is obviously taking quite a market share off the stop smoking services and we don't have the budgets to combat the quite aggressive marketing of electronic cigarettes. So the things we can offer, like the expertise of our staff, and that counselling and support and so on, and weaning off rather than the regular use of nicotine with electronic cigarettes, we are struggling to combat that, and the prominence of the services has been kind of hit by that and I think we feel a bit let down that we haven't had anything to, not to counter it because on the whole I think they are probably a good thing, but I don't think particularly for women who are pregnant it is a good thing to be on any form of nicotine; with the constriction of vessels and the increased metabolic rate with nicotine, so that has been quite a blow in a sense to the services. Although in terms of the prevalence of smoking nationally it is possibly a good thing, I am not so sure whether it is a good thing for pregnant women.

SSS manager 1, SSS C, Interview, 30th June 2014

A further contradiction was the lack of support for the SSPS from government, in the face of huge investment by private companies into marketing e-cigarettes and the rise in their use (ref). It was known that e-cigarettes continued to deliver nicotine and sustain smoking habits, which it could be argued, were detrimental to fetal health e.g. raising fetal heartbeat (ref). At the time, SSPS did not recommend the use of e-cigarettes but they had no better alternative (Chamberlain *et al.*, 2013). Since then, more research has been completed and they are now an accepted part of harm reduction from smoking in the UK; however, so far, all that has been concluded in pregnancy is that they 'pose potential threats' to the fetus (Chamberlain *et al.*, 2013, p5; PHE, 2015b; RCP and TAG, 2018). Although not tested with pregnant women and therefore not officially promoted, it is assumed that they would reduce harm - compared to tobacco - to the woman and fetus in the same way as for any smoker (Chamberlain *et al.*, 2013; PHE, 2015b; RCP and TAG, 2018). The evaluation was not set up to include consideration of electronic cigarettes because their rapid adoption was not anticipated; however, they are mentioned here as part of the context at that time.

In summary, nationally there were legislation, media and publications to support the stopping smoking argument; however, there was reticence from some maternity services to deliver it on the frontline. Simultaneously, e-cigarettes were becoming popular in society, but their effects had not been researched.

7.3 Regional context

Please refer to Appendix 11.2.4 for additional information and references for this section.

7.3.1 Regional media campaigns

Fresh NE conducted an intense media campaign, directed at adults as family members and the impact of their smoking not only on themselves but their families too, during the evaluation period. They were successful in attracting attention across a wide number of national and regional media outlets, including television, radio and newspapers. This supported the work on the stop smoking agenda in maternity and stop smoking in pregnancy services.

7.3.2 Changes at the macro level

Change in funding, commissioning and providing services has been led by government and affects England as a whole. How this has affected the region and the timing of changes in relation to the implementation of babyClear© is outlined below.

Changes in commissioning organisations

Strategic Health Authorities, the organisations tasked with co-ordinating regional efforts to improve health, were dissolved in 2013 (DH, 2012). The government also moved responsibility for the public health agenda from PCTs to LAs when they introduced the *Health and Social Care Act* (DH, 2012). PCTs, the commissioning – and sometimes providing – body for primary care health services, were officially dissolved on 1st April 2013, with all the associated reorganisation required, just as the implementation of babyClear© was starting. The new commissioning organisations, CCGs, were yet to be established and took many months, even years, before they were operational. Two excerpts from my field diary, noting conversations I had with concerned senior HCPs at this time, demonstrate the point:

> *[Lead pharmacist] talked about when Andrew Lansley brought in the White Paper there was no mention of pharmacies at all, whereas before they had been steaming ahead with the PH agenda, in the direction set by the Labour government and pursued locally by the PCT. With the introduction of CCGs this had stopped and CCGs were still finding their way.*

BabyClear© training event, Diary entry, 18th September 2014

Chatted with [SSS commissioner] who has found LA PH systems are not sufficiently quick and flexible to meet PH needs, unlike PCTs which were much more responsive. It has meant that people have been left without services e.g. between contracts. The LA committee system is slow and laborious.

PHE event, Durham, Diary entry, 18th November 2014

On the frontline it involved many changes:

Interviewer: And is there an element in which the community midwives maybe are not very confident in the stop smoking service that they are referring people to? …
PT: … So, I think the midwives suddenly had to go from an old service that they didn't feel was like doing very well, to suddenly having to send all these women to pharmacy because that was the best thing we could do, because we didn't have anything else. And it is going to change again now because stop smoking are going to pick them all up again now, so it is going to change again, but they don't know that yet, cos I haven't told them. So, after Christmas, I am going to go back and say, look I am sorry, we know that has not been working well, … this is the model that we are now going to follow. So I think they have been through loads and loads of change, and what the hell is going on?

Interview, PH midwife 2, Trust D, 23rd December 2014

Interviewer: Do you think that it's going to change again, the stop smoking service?
PT: Yes, I think it probably will. Yes, it will. There'll be a new model. I don't know what that new model will have in it, so we don't know…. We're up in the air at the moment because the council are commissioning the stop smoking service now, it's not the NHS.

Interview, Specialist Stop Smoking Advisor 5, SSS H, 9th December 2014

SSPS staff were living in uncertain times, which affected the quality of the service they were able to provide. Midwifery confidence in the process and quality of SSPS on offer was reduced by all the changes; which truncated the babyClear© pathway and undermined the implementation.

Changes in provider organisations

Generally, recommissioning involved new SSPS structures that aimed to provide high quality services more cost effectively. I noted the discussion at a workshop I organised to gain feedback on the preliminary evaluation findings, where PH staff in LAs and provider organisations expressed their opinion as to where CCGs' focus lay:

Mention of how CCGs are budget focused, no other measure that they are interested in … reminded me of the Royal College of Nursing keynote

speakers, the result of this attitude is … care and quality go out the window. Making the money-argument reminds me of the sub heading in the NPT paper "he who pays the piper plays the tune" (Kennedy et al., 2014).

Diary entry, May 19th 2015

This new commissioning system led to a time of huge uncertainty, change and organisational paralysis; the new CCGs were not in a place to engage with LAs or providers for an extended period, causing me to reflect further:

The absence of [attendees from] CCGs was discussed; not surprised but I was still disappointed [by their lack of attendance]. Since then I have noted in the PHE/ASH seminar report, which covered the whole country, that they experienced much the same problem – so it is clearly a problem far beyond our little workshop. Their report does suggest some reasons but primarily this is definitely an issue that requires addressing … with no CCG input or exchange how are they going to commission in a well-informed manner?*

Diary entry, May 19th 2015

*PHE/ASH conducted a 'roadshow' that toured the country on the single issue of stop smoking.

Staff were left with the threat of unknown change hanging over them before decisions were finally taken, often involving job losses or significant changes. Early in data collection, I noted in my diary how I had prioritised visiting SSS D because:

… jobs were in the balance at this point in time; it was while they were waiting to see who had bid successfully for the contract for the SSS; if they would keep the contract or if it would go to another bidder.

Diary entry, 21st January 2014

One member of staff said:

PT: … Been in post 8 years, originally started in [SSS C] then TUPE-ed over to [SSS D] when [SSS D was re-structured] about 5 years ago.
Interviewer: And are you a specialist in pregnancy?
PT: No. Our pregnancy advisor left in November of last year and so I am at the minute the only advisor because we have been decommissioned and we have been out for tender. So I am at this moment in time the only advisor in the service.

General stop smoking advisor 1, SSS D, 13th February, 2014

Some LAs decided to tender for providing SSPSs themselves while others did not; provision then moved to LAs or other providers, depending on who won the contract awarded by the CCG. On talking to an employee of a 3rd sector organisation who had won the contract to provide SSS (including SSPS) in one Trust area, I wrote:

> *… found out [Trust H] SS re-commissioned with [3rd sector organisation]. They have never offered smoking cessation before. In for 6 months now. LA had to work with them closely to devise new model; sounds like [SDM 3] and using existing workers in the community. I did mention about need for close follow-up after RPT but they agreed it was not being offered. I had said funding withdrawn but they contested this; however did agree that the service had collapsed pretty much, although the commissioners had asked them to carry on. Some unrealistic expectation here; everyone was leaving or at least looking for new jobs when I was there interviewing in December 2014.*

PHINE event, Diary entry, 9th May 2016

This all took a long time and participants reported that neither the LAs nor the CCGs were able to act due to the reorganisation and this impacted the future of babyClear©. Trust D was one example, where I interviewed a SSPS specialist advisor who had taken over after a very experienced specialist had left:

> *Because I mean the problems we're having with [the] stop smoking service at the moment, we don't know where we are really. I think it [babyClear©]'s going to be difficult to sustain it, to be honest.*

Specialist Stop Smoking Advisor 5, SSS H, 9th December 2014

Furthermore, it was reported that it had become more difficult to promote the SS agenda because the PCT was public health focused, whereas LAs and Trusts had different priorities, as mentioned above. This was illustrated in one area by the way the Trust Chief Executive had become further removed from the SSS manager with layers of middle managers now in between, whose priority was not the SS message.

> *But even if [babyClear©] is found that it has helped a little bit but it hasn't made a huge difference to the overall picture, it won't be my decision as to whether this is the way we operate because now that….I was more involved in the strategic decisions early on, where those strategic decisions were made more on an equitable partnership basis between services and commissioners.*

SSS manager 1, Trust C, 30th June 2014

The changes in provision were not anticipated by the implementers of babyClear© and participants reported that they were unsupported in managing the two at once, on the frontline. Midwives, MCAs and SS advisors neither had the power or authority, nor were they the decision-makers, regarding changes to service provision. They had to continue to work within the available resources but were conscious that they were unable to provide pregnant smokers with the quality of care, especially in terms of feedback and follow up, that they aspired to.

Changes in funding of services

BabyClear© was introduced within a nationally imposed context of fiscal austerity. I noted that many PH researchers were presenting data to their peers that was profoundly disturbing:

> *The need to fight for funding of PH – absolutely shocking evidence of how the LA budgets have been cut in non-Tory voting areas, bearing in mind how PH is now funded from LAs. Wild scramble for funding, passing of responsibility between NHS/LAs and different agendas and priorities of elected council members as compared with PCTs.*

SPHR Annual Scientific meeting, Diary entry, 11th March 2016

Staff were very aware that there were no extra resources available for new initiatives; one of the selling points of babyClear© was that it came with all the resources attached. An excerpt from the letter sent to all Trust Chief Executives in the NE region in August 2013, to update them on progress and engage them to continue their support, follows. It details the resources provided by the funders of the babyClear© package:

> *This programme, based upon NICE guidance and developed to address specific issues identified by North East midwives themselves, has involved working predominantly with midwives and Stop Smoking Services (SSS) to:*
>
> - *Train all community midwives to deliver very brief interventions on smoking (three minutes or less) at the first booking appointment with pregnant women. This will focus on systematically testing all pregnant women for signs of carbon monoxide and implementing an opt-out referral system to the local NHS SSS*
> - *Provide appropriate equipment, promotional materials and written information for midwives*
> - *Develop localised protocols, care pathways and monitoring systems*
> - *Deliver advanced training to a much smaller cohort midwifery champions who wish to deliver a more intensive "risk perception" intervention around smoking at time of dating scan appointments*

- *Provide tailored training to Stop Smoking Service advisors and admin staff to ensure that all pregnant smokers are given access to the best support to quit as quickly as possible.*

Maternity services nationally were in a constant state of threat from short staffing and closure of beds (Appendix 11.2.4). There were local examples too at Berwick, Darlington and Bishop Auckland, where temporary closures took place and a review of requirements was expected (Appendix 11.2.4).

Nationally, strategic decisions associated with healthcare delivery were made by responding to specific directives from government. These reflected the political agenda, which was implemented by Payment by Results (PbR) and CQUIN guidance (Appendix 11.2.4). These methods controlled funding for services, and therefore directed where effort and resource were focused:

> *It [stop smoking] doesn't come with any financial money, literally how maternity is getting its funding is totally by payment by results, PbR, and that is a funding for standard, intermediate and enhanced, and stop smoking is not, not credited with anything really, so you'd only get standard payment, even though these women can actually take double the amount of visits with the [maternity care assistants] and intervention and risk perception.*

Senior Manager 3, Trust C, 15th September 2014

PbR paid SSPS by quit rate and did not offer extra payments to maternity services to care for smokers even though there was strong evidence that smokers and their babies experience poorer health and have worse outcomes in pregnancy than non-smokers (RCP, 2010). Therefore, this made it vital for maternity services that women quit and experienced healthier – and less costly - pregnancies (Appendix 11.2.4). Although this can be seen as an incentive to promote wellbeing amongst pregnant women, in areas serving populations living in high deprivation, statistically there were likely to be more smokers who would also find it harder to quit (Shipton *et al.*, 2009), putting these services at risk of being disadvantaged financially.

PbR in community SSPS were in a similar situation; providers e.g. pharmacies, outreach workers, public health nurses, are paid per quit at 4 and 12 weeks; so, a smoker who requires extra support is a drain on their resources because the extra effort is not reflected in extra income.

> *… the last fee is quite a substantial fee, so that's £15 to register, I think it's £35 at four weeks and I think it's £37 at 12. So you're more or less nearly*

doubling your total fee to get it, so there is, there is that [incentive] currently in the service that does, yeah. But no, as I say, it needs to be quality based now rather than quantity based actually.

Interview, Lead Pharmacist, SSS B, F & G, 18th September 2014

The financial environment in which midwives, MCAs and SS advisors were delivering babyClear© was one of gloom and threat; and a heightened awareness among managers about the day-to-day cost of running the services. This was recognised by the implementers, who included equipment and training within their offer. Cheaper ways to provide services were continually being sought and staff struggled to maintain quality of care e.g. during extended contract negotiations and setting up of altered SDMs. Long-term savings to the NHS, through sustaining improvements to patient health, were not valued or incentivised.

7.3.3 Changes at the meso level

Changes in service delivery model

Maternity and stop smoking in pregnancy services are required to work together to meet pregnant smokers' needs (NICE, 2010). The impact of the combined effects of these funding frameworks and the current commissioner-provider model on both services in terms of service integration (DHSC, 2018b) was reflected in these comments from an SSS manager:

Interviewer: Yeah, about where that boundary lies between Stop Smoking Services and Maternity Services, and it's drawn in a different place in every area.
PT: Absolutely, and I would say, you know, there has to be some meeting because obviously the Stop Smoking support is intricately linked to the pregnancy pathway that that woman's going to be on and the tariff that's attached to delivery. So I don't think you can say it's just a public health issue, you deal with it; I think there has to be some sharing of responsibility and resources.

Interview, SSS manager 2, SSS B, F & G, 6th August, 2014

One major factor impacting services was the multiple SSPS delivery models being introduced across the region (see 7.4). The main issue of relevance was that the babyClear© package was a standardised intervention that made certain assumptions about the SDM (see 6.2); however, if these assumptions were not met it created a challenge. There were other, associated considerations too e.g. the beliefs/evidence behind alternative SDMs that determined their structures. Some did not accept that pregnant smokers were a sub-group of

all smokers, with specific requirements, who did not respond in the same way as usual clients and therefore required different approaches.
As explained by one SSS manager:

> *… this is where perhaps, even within the Stop Smoking Services there is a little bit of a difference in opinion on around how pregnant smokers are treated. One of those would be you're only treating the smoking and supporting them to stop; therefore, there shouldn't be any difference to anybody else in the population. The other school of thought is that actually there are a whole lot more complexities when people are pregnant that makes it more difficult for them to stop smoking, particularly in the North East of England, where we do have higher levels of smoking at time of delivery, particularly in younger mums. That generic approach doesn't necessarily fit very well with the way that services would be delivered. And it might be worth adding that in [large town 1, large town 2] and [Locality 11] there are no specialist Stop Smoking Services; that was entirely decommissioned, and the way services are delivered is through what we would call active intervention or AI [active intervention] providers. What the AI providers do is they deliver, they're contracted to deliver a service to the entire smoking population, of which pregnant smokers are a subset.*

Interview, SSS manager 2, SSS B, F & G, 6th August 2014

In addition, the SSSs – which included pregnant women among their clients - were under pressure to show themselves to be cost-effective very quickly to improve their chances of having their contracts renewed, so it was not in their interest to devote extra time to pregnant smokers. This is reflected in quotes about the macro level context concerning decisions to change SDMs and also in a chat I noted down in my diary with SSS manager 2:

> *[She] hinted that the model was about to change again, so it would be better to talk sooner rather than later …*

Fuse Quarterly Meeting, Diary entry, 21st July 2014

Variation in contexts also affected training sessions; although they were valued for increasing coherence, skills and engagement with babyClear©; analysis highlighted several ways that they had been devalued. ‘Mop-up’ sessions had to be added as accessibility for staff at centralised locations, within the constraints of their working days. There was low plasticity in the training plan and protocol to adapt to the situation on the frontline. Low plasticity, as defined by May, Johnson & Finch (2016) (see 3.8), within the intervention, affected sustainability because they were unable to flex with local conditions (see 9.7.1).

In summary, Fresh NE was very active in the region, disseminating the stop smoking message through multiple media to complement the implementation. Nevertheless, national

changes in legislation strongly influenced regional services. How they were funded, who commissioned and provided them, planning of training and what was delivered all changed dramatically, as illustrated through the quotes. Managers worked hard to introduce and optimise their SDMs. However, implementing an enhanced, standardised, babyClear© pathway, within many different environments, in conditions of financial austerity and short-termism, complicated the process.

7.4 Local variation

The evaluation showed in different ways how there was significant variation within the NE region. Although the region had higher SATOD rates compared to all other regions (20.6%) in 2011/12, there were local variations from 15.8% in North Tyneside to 28.2% in Middlesbrough (NHS Digital, No date) (see 1.8.2).

7.4.1 Local structural changes

BabyClear© was being introduced into a national context whereby NHS budgets were being cut but Trust organisations were expected to maintain quality (Appendix 11.2.4). Local, smaller, maternity units were under threat of closure or already temporarily closed (Appendix 11.2.4). HoMs explained how they were under enormous pressure, some were 'acting-up' and two were new in post. I found it difficult to contact some of them, their email inboxes were full and messages went unanswered for various reasons. Reflecting on one interview in my diary I noted:

> *When I asked about unanswered emails [due to work overload] to the directorate manager and head of midwifery about taking part and approval of the data for an academic purpose she said they would expect her to pick those queries up. However, I had not cc'd [PH midwife] in.*

Interview, PH midwife 2, Trust D, 23rd December 2014

There appeared to be little prioritisation in some Trusts of the SS message and the need to ensure that training in babyClear© was well organised; one SSS pregnancy specialist attended a booked meeting only to find the HoM had cancelled it, but not made her aware:

> *And even looking ahead before we'd had the first training about the risk perception that was coming, it was like [the Head of Midwifery said …] yeah, yes, alright, we'll do that, well, you know, I don't know how we're going to implement that, I mean it's going to be impossible, blah, blah, blah. And I said well, you know, if we had a meeting and sort of saw, yeah, right, okay, we'll do that, I'll send an email out to various people. So, I got a copy of the email of some of the people, I don't know who they were in it, went along to the meeting, nobody turned up. Nobody turned up. And*

> *then eventually about half an hour later the deputy turned up and said, oh, [senior manager 4] can't come, did she tell you so-and-so wouldn't come and this. Well, we'll just have a chat, you know. I thought, I changed all my day and really and done all this, come there and really it was lip service, it was nothing.*

Interview, Specialist Stop Smoking Advisor 3, SSS E, 17th July 2014

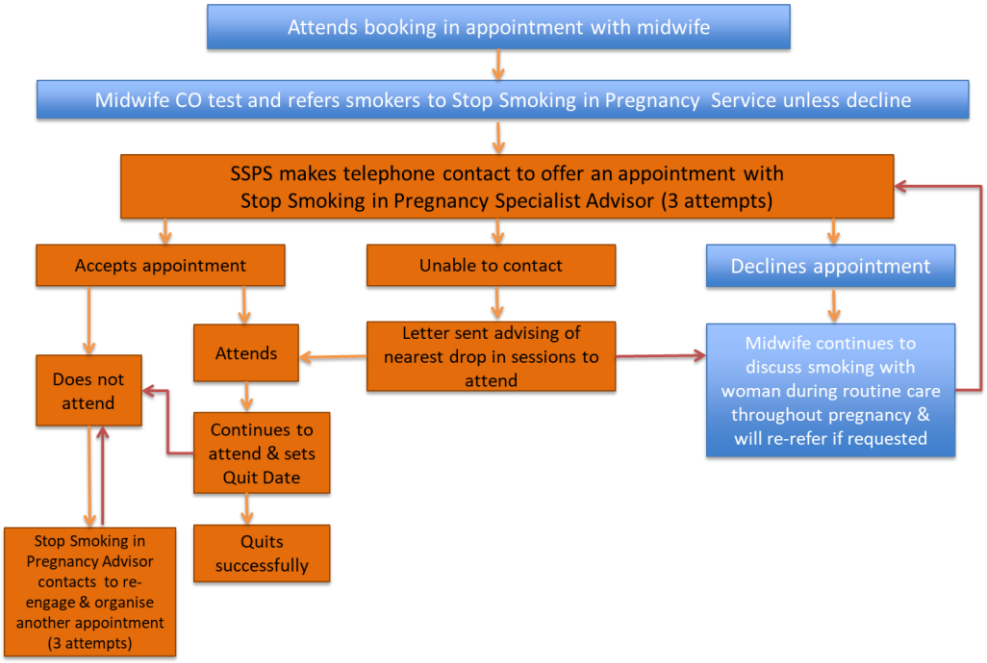
In summary, national austerity measures threatened local services, senior staff were overloaded and gave priority to other issues than stop smoking. In this environment, it was difficult for the implementation to make headway, especially when it became clear that it was more complicated to operationalise than expected, as explored below.

7.4.2 Local service delivery models

There were variations in the service delivery models (SDMs) in place prior to the intervention, both in terms of maternity and stop smoking provision. As babyClear© was implemented, the organisations sought to make changes to allow it to become embedded. This process varied from one service to another. The different models and their key characteristics are shown below (Figures 7-2–7-6), the detailed differences within each Trust and some comments on how maternity services responded to the implementation - drawn from interview transcripts, additional notes and the researcher's field diary - are in Appendix 11.2.5.

Figure 7-2: Service Delivery Model 1

Pre babyClear©: Trusts A, E, H & J



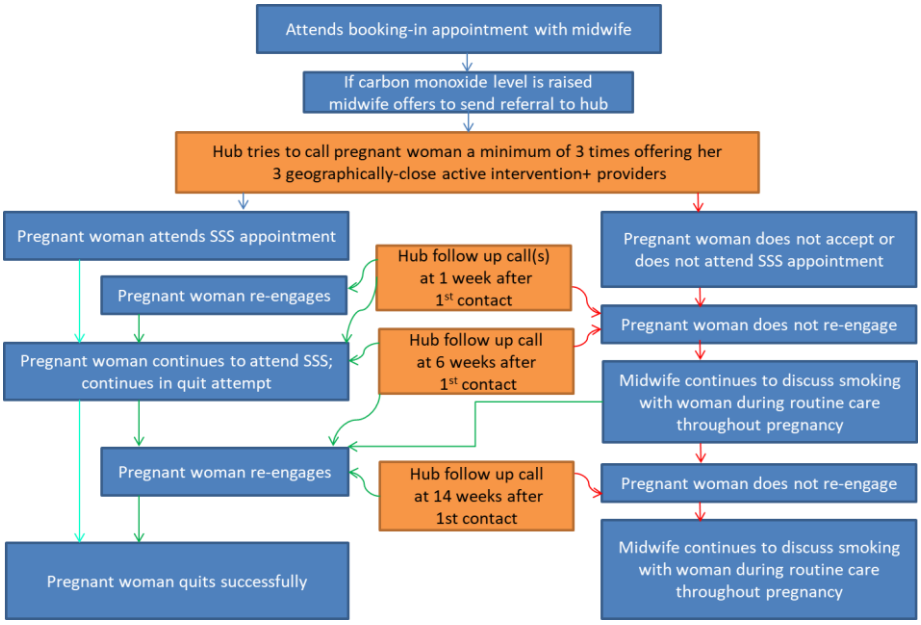
SDM 1 – Key characteristics:

- First contact at booking-in appointment
- Specialist pregnancy stop smoking advisor
- No Maternity Care Assistants.

This model was broadly the same as the standard delivery model assumed by the designers of babyClear©. Significantly, there was a specialist pregnancy advisor to refer women to, but it did not hold with the assumed standard in terms of the presence, within the hospital antenatal clinics, of a midwife with responsibility for stop smoking or a midwife in the dating scan clinics, suitable to deliver the RPT. Although Trust H broadly shared this model, it had multiple maternity consultant and scan clinics instead of discrete dating scan sessions.

Figure 7-3: Service Delivery Model 2

Pre babyClear©: Trusts F & G

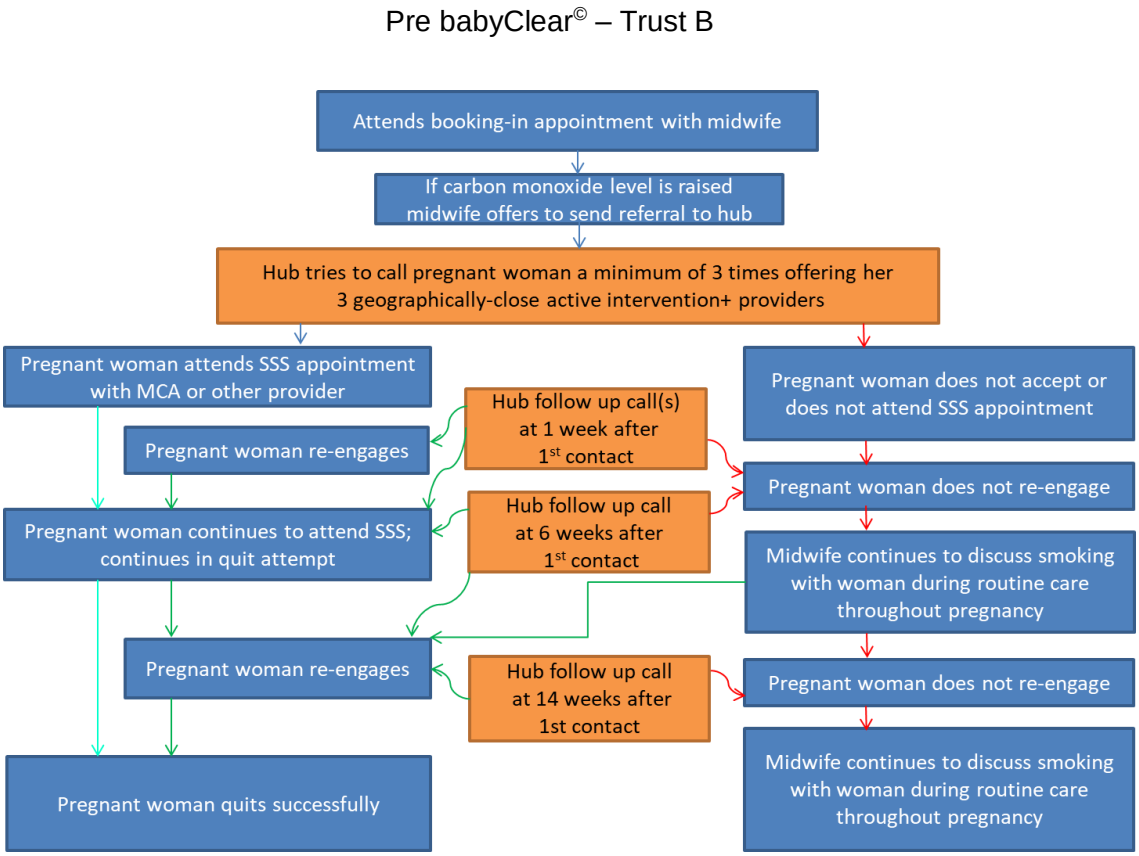


SDM 2 – Key characteristics:

- First contact at booking-in appointment
- Hub with mentors, general advisors provided by multiple community agencies
- No specialist pregnancy stop smoking advisor
- No Maternity Care Assistants.

This model was the one most radically different from the standard. It had been recently introduced and was on a trial basis. The key difference was the SSS structure. It centred on a ‘hub’ which offered administrative support and SS mentors but no SS advisors. Advisors were provided by community organisations who were commissioned as providers.

Figure 7-4: Service Delivery Model 3



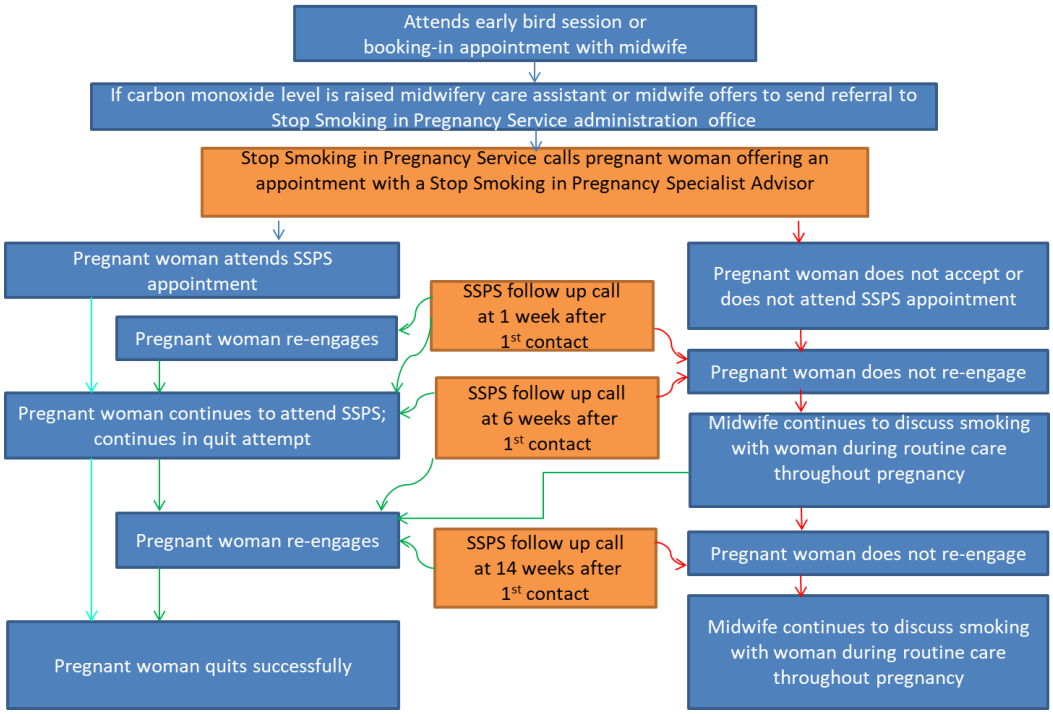
SDM 3 – Key characteristics:

- First contact at booking-in appointment
- Hub with mentors, general advisors provided by multiple community agencies
- No specialist pregnancy stop smoking advisor
- Maternity Care Assistants.

This model was like SDM 2 with a 'hub' structure and no advisors directly provided by the SSS; however, the maternity service provided some SS advisory support by MCAs.

Figure 7-5: Service Delivery Model 4

Pre babyClear©: Trust D

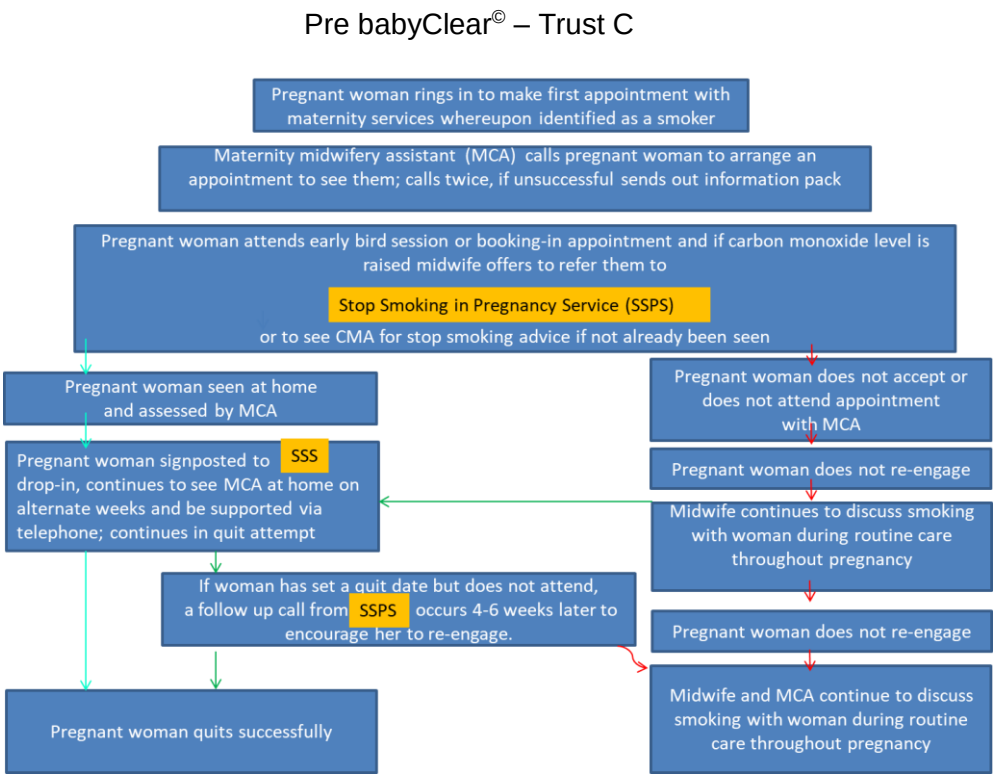


SDM 4 – Key characteristics:

- First contact at pre-booking-in appointment
- Specialist pregnancy stop smoking advisor
- No Maternity Care Assistants.

This model was like SDM 1 except that maternity services provided pre-booking (early bird) sessions for pregnant women. This model had multiple maternity consultant and scan clinics instead of discrete dating scan sessions. The SSS was being recommissioned at this time.

Figure 7-6: Service Delivery Model 5



SDM 5 – Key characteristics:

- First contact at pre-booking-in telephone call
- Specialist pregnancy stop smoking advisor
- Maternity Care Assistants.

This model was well-established and integrated maternity and SSS more closely; starting with an introductory telephone call from an MCA shortly after referral into maternity services. It relied heavily on MCAs who had an extensive SS remit.

7.4.3 Comments from the data on local variation

Regional services thus used a variety of different SDMs. Different key characteristics are summarised in Table 7-1.

Table 7-1: Key characteristics of service delivery models

SDM 1	SDM 2	SDM 3	SDM 4	SDM 5
First contact at booking-in appointment	First contact at booking-in appointment Hub with mentors, general advisors provided by multiple community agencies	First contact at booking-in appointment Hub with mentors, general advisors provided by multiple community agencies	First contact at pre-booking-in appointment	First contact at pre-booking-in telephone call
Specialist pregnancy stop smoking advisor	No specialist pregnancy stop smoking advisor	No specialist pregnancy stop smoking advisor	Specialist pregnancy stop smoking advisor	Specialist pregnancy stop smoking advisor
No Maternity Care Assistants	No Maternity Care Assistants	Maternity Care Assistants present	No Maternity Care Assistants	Maternity Care Assistants present

Some SDMs had been developed over time, others were a response to recent commissioning changes. This included variation in follow-up options in terms of:

- time of initial referral
- who makes the initial referral
- who administers the initial referrals
- midwifery role that delivers the RPT
- role that provides immediate SS follow-up to RPT
- length of time to first follow-up after RPT
- role that provides SS follow-up in the community
- venue for follow-up
- length of follow-up.

This variety created enormous confusion and uncertainty for staff and pregnant smokers, which was increased with babyClear©. This was apparent at an observed training session for SS advisors where HCPs were questioning how babyClear© could be implemented in their area, due to the mismatch of models. There appeared to have been no recognition by the developers, trainers and commissioners of the widespread differences and the impact they would have on the implementation. Neither was there an existing systematic process to collect this information beforehand. The resulting inability to introduce all the procedures in the ways envisaged, led to *ad hoc* interpretations locally e.g. variation in the script and in follow up options.

> *Contacting the customers and it was trying to stick to the script and that doesn't work when you stick to the ... majority of the patients that we get ringing up.*

Interview, Administrator 3, SSS E, 17th July 2014

Access to NRT varied across SDMs; some were quicker than others. If a smoker was seen by a prescriber in a clinic e.g. an SS advisor or SS trained midwife, they were given a prescription. However, although MCAs conveniently carried out home visits, they were unable to sign prescriptions; vouchers were issued instead. These needed to be presented at another SS clinic or a named pharmacy, depending on the SDM, before they could be dispensed.

In some areas the SSS was unavailable due to recommissioning:

> *What happens now, because we have had to use pharmacies, as you rightly said, because we haven't had a service up until now…*

Interview, PH Midwife 2, 23rd December 2014

Other areas were struggling to sustain the pathway due to restructuring:

> *PT 124: She always had a lot to do from when she started with the pregnancy. But I think our main one we lost, didn't we? The main one because she was midwife trained as well, wasn't she?*
> *Interviewer: So, was that through cuts or did people just retire or?*
> *PT 123: No, it was from reconfiguration of the service.*
> *Interviewer: Yes.*
> *PT 123: So, we lost quite a few people who used to …*
> *PT 124: Deal with the pregnancy visits, wasn't it?*

Paired interview, SSS administrators 5 & 6, SSS H, 9th December 2014

Some areas were constrained by SDM design:

> *Right, Ok, it depends on the provider. So, we'll hold information to a degree on the times that that provider might be open or able to offer a service, but we can't book appointments directly. And that's because of the governance around the system that we use; we can receive information from the Maternity Services staff, but we can't then pass that on to anybody else. So, we would ring the pregnant lady, provide lots of motivational support and encouragement to try and get them to access the nearest Stop Smoking provider, but we don't necessarily know whether they did that or not.*

Interview, SSS manager 2, SSS B, F & G, 18th September 2014

> *…it's like what we said before about, you know, needing to be more located so that we can give them more time, because if they are outside of our area it's really difficult. We'll go and do the support and then we'll have to come back because of commitments and then the rest of our role.*

Paired interview, Community Outreach Worker 1, SSS G, 18th December 2014

Some areas were constrained by changes in funding:

> *The local authority pulled their funding for the maternity support worker that was doing it.*

Interview, Senior Manager 7, Trust F, 15th January 2015

> *…helping women, pregnant women, to quit and set quit dates. And that's still very active in [Trust A] but unfortunately in the south of the Trust that provision's no longer there. And we have a massive gap where the girls have got no capacity now.*

Interview, Senior Manager 1, Trust A, 5th August 2014

Some SDMs did not maintain contact up until NRT had been provided but instead left it up to the smoker to follow-up:

> *I think there's something really important about the phone call that we make to say we're ringing you about your treatment for stopping smoking but then we can't say where you're going to have it or who with. We can say, right, up to you now and I think perhaps it loses its impact a little bit. The importance of that message maybe gets diluted by the fact that that person's left to their own devices to seek appropriate help.*

Interview, SSS manager 2, SSS B, F & G, 18th September 2014

> *...when they say, yes, I'm going to attend this clinic, and some of them are drop in clinics. So, they don't actually have an appointment or for our advisors in GP clinics. So, if it's a GP clinic, the GP receptionists hold the appointments. So, we can't say, we'll give you this appointment. So, we've got to rely on them saying, you want to go to your GP? Yes, that would be the best. And then it's, well you're going to have to phone your GP and make an appointment, and that's not really ideal.*

Paired interview, Administrator 5, SSS H, 9th December 2014

The vision for babyClear© did not reflect the reality of the systems staff reported that they were working within. Improving delivery of NICE guidance (2012) was expected in non-conducive contexts e.g. where SS specialist provision and MCA support was often lacking, information governance decisions restricted sharing of data and where access to services for pregnant smokers was impeded.

Data collection plans had to be revised due to lengthy implementation delays. The intention was to speak to participants after the babyClear© package had been fully implemented in their organisation. One Trust was quicker to implement it, three more followed, but the other four Trusts struggled and the time for data collection passed before the RPT was up and running. Therefore, in later implementing Trusts, I collected data only from senior and middle managers. Data were collected at different time points in the implementation cycle but were not treated as multiple datasets; the later data were used to reflect on the earlier data and consider the elements that promoted normalisation and sustainability. This was with a view to identifying the reasons for delay. I did not interview other maternity staff as it would have reduced rigour, since they would not be reflecting on implementation of the full package. Similarly, the SSPS in some areas had greater capacity than others to handle the increased volume of referrals and the intensified follow up. In part this was due to re-structuring of the SSPS. So again, I revised the timetable to reflect this and re-arranged to interview people once the new package and structures were beginning to become established.

7.5 Summary of context

Although pressure from the demands of government at the macro (national) level was similar, there was broad variation in the implementation context at the meso and micro levels. The geographical areas, the demographics of populations, the history of local SSPS systems, the SDMs designed to respond to local need, the individual staff members – all played a significant part in creating a diverse landscape into which a standard package of measures, babyClear©, was expected to slot. The data showed that local, contextual variation had not been considered sufficiently and the 'workability' of the intervention was questioned, making implementation much harder to achieve than anticipated.

7.6 Comparison of hypothesised mechanisms and actual findings

The mechanisms of impact, based on the logic model i.e. the planned implementation, are stated in Chapter 6. An example of deriving an active ingredient from the thematic analysis can be found in Appendix 11.5.2. Table 7-2 summarises the active ingredients with more detail of the analysis given below.

Table 7-2: Summary of active ingredients

Mechanism	Description
1	Carbon Monoxide (CO) monitoring required availability and acceptance of the new CO analysers, which included staff and patients believing them to be accurate. Introduction of a catch-all threshold meant that any pregnant woman who was potentially at risk from CO, including from smoking, was more likely to be referred.
2	Opt-out referral required high numbers of staff to be trained to babyClear© standards in the new approach. Implementation required the backing of effective performance management and feedback loops to reveal referral compliance levels.
3	To allow speedy referrals to be made, systems that allowed quick, early referrals were required. Organisations that were well integrated and facilitated feedback loops enabled a faster referral system.
4	To embed the total quit message smokers needed to be empowered to accept and act on the 'quit completely' message.
5	Restructuring and resourcing of systems was necessary to enable quicker timeframes to support an increase in quit rates.
6	Maternity and stop smoking in pregnancy services staff who were trained in motivational interviewing and accepted the new discourse were more likely to use it to engage successfully with women to challenge their smoking habits.
7	Increased contact was enabled in SSPS with resources and systems that flexed with the pregnant women and in maternity and stop smoking services that were well integrated and operated robust feedback loops.
8	Believing in the effectiveness of the Risk Perception Tool (RPT) and thinking creatively about how to implement this tool were thought to make it more likely that quit rates would increase.
9	Not known.
10	Maternity and stop smoking in pregnancy services staff who were well-suited to the work, with an adaptable approach and training in motivational interviewing, were more likely to increase quit rates i.e. training in mechanism 6 – the new discourse, which has the same facilitators and barriers.
11	Well-resourced contexts where NICE PH Guidance (2010) was already more embedded were perceived as more likely to increase quit rates.

This sub-section will now take each logic model-derived mechanism and present those findings in terms of:

a) evidence from NICE PH Guidance (2010), supplemented by the wider literature, for the mechanism of impact for each procedure

b) a summary of the findings from analysing the example dataset, noting the active ingredients, barriers and facilitators for each procedure, making explicit what was implicit from trials evidence
c) comment on the effect during implementation of the actual setting on the hypothesised mechanism for each procedure (revealing the theory-practice gap).

7.6.1 Mechanism 1 - Carbon Monoxide monitoring

How does the introduction of a new CO analyser and lower acceptable level of CO increase quit rates?

The evidence:

- CO monitoring itself has been shown to be a suitable way to identify smoking status (NICE, 2010, p49).
- Motivation to quit has been shown to increase with a visual message (Sloan *et al.*, 2016).
- Visual media such as graphic pictures that shock are thought to give a stronger message than text (Hoek and Jones, 2011; Hoek *et al.*, 2012; Hoek *et al.*, 2014).
- Public health warnings posit a link between increasing perception of threat and changing behaviour away from the activity (Peters *et al*., 2013).
- NICE PH Guidance (2010, p44) recommends that more detailed and explicit SS messages are conveyed.
- The ideal cut-off point for determining smoking status through CO analysing has not been established (NICE, 2010, p6), however the recommendation is to increase referral rates into SSPS (NICE 2010, p22). Lowering the cut-off point will automatically increase the number of women fulfilling the criteria for referral.
- Evidence exists that being supported through SSPS increases the probability of a successful quit for a pregnant woman (NICE 2010, p47; West and McEwen, 2012).

Therefore, by using CO analysers which promote a more urgent and threatening message, and by referring more pregnant women with a positive CO reading, it is thought that more will decide to quit.

Active ingredients

CO monitoring required availability and acceptance of the new CO analysers, which included staff and patients believing them to be accurate. Introduction of a catch-all threshold meant that any pregnant women who was potentially at risk from CO, including from smoking, was more likely to be referred.

Facilitators	*Barriers*
Greater availability of CO analysers Design of new analysers Robust system to equip new staff, hospital staff; repair analysers; provide batteries Compliance with documentation Perceived benefit of new analysers	Contradictory information regarding new lower CO threshold Faulty analysers Design of new analysers System unable to ensure provision of CO analysers as and when required Poor standard of documentation Perceived inaccuracy of analysers

Some maternity staff found the new analysers beneficial, easier to use and more appealing to women:

> *...it's an easier machine to use; it doesn't need to be calibrated. I don't have a problem with it.*

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

Other maternity staff saw them as less beneficial and not so easy to use:

> *I don't like them, no, I think it's complicated and trying to get pregnant women to hold their breath for 15 seconds is a bit difficult really and they just don't understand, what you're saying to them and they do it wrong, we've tried all sorts of ways of instructing them on how to do it. The old monitors were much easier.*

Group interview, Community Midwife 5, Trust C, 15th July 2014

Concern over their accuracy was mentioned several times and staff either did not always trust the readings or did not follow up high readings appropriately. The main inconvenience reported by maternity staff was the short life of the batteries. With the intervention, the CO threshold was lowered – and so would include anyone whose levels were only slightly raised; however, there was some confusion over the new cut-off point:

> *...there was some confliction [sic] between what a high CO reading was and what wasn't ... 'cos in the training we were told 3 and then when all the literature came out it said 4, and I think that was a bit confusing.*

Interview, PH Midwife 2, Trust D, 23rd December 2014

Summary

1. Introduction of new CO analysers was not uniformly accepted.
2. Some maternity staff preferred the new analysers, but others did not; specifically, short battery life, faulty equipment and concerns over accuracy were widespread issues.
3. A lower threshold for referral was introduced, although the exact level was unclear.

Organisations differed in terms of:

a. Variation in equipment and monitoring prior to implementation.

Individuals varied in terms of:

a. Response to monitoring, to the new analysers, to framing the conversation, to documenting readings.

Effect of the setting on the hypothesised mechanism

Without full acceptance of the new CO analysers and clear guidelines on the lower threshold, it was expected that quit rate increases would be negatively impacted. Variations in context introduced variability regarding the effect of the setting on this mechanism.

Key findings

Maternity staff talked about normalisation of CO testing; partly due to high specification analysers being made available to all relevant maternity staff. This evidence is supported by SSPS staff, who reported a dramatically increased referral rate. Although there was confusion over the referral threshold due to communication of different cut-off points. Nevertheless, maternity staff reported that routine CO monitoring gave them a positive way to introduce a new discourse. In their opinion, it also gave pregnant smokers something to aim for and so encouraged them to quit. However, the analysers' functionality in everyday use was questioned.

7.6.2 Mechanism 2 - Opt-out referral

How does opt-out referral from maternity services increase quit rates?

The evidence:

- Nudge theory suggests that people can be subtly persuaded towards certain choices by the way a factor is structured e.g. a building or a system (Blumenthal-Barby and Burroughs, 2012).

- Opt-out is recommended by NICE PH Guidance (2010, p49) and thought to increase motivation to quit, by being presented as part of normal treatment (Sloan *et al.*, 2016).
- Pregnant smokers as a group are more likely to exhibit an external locus of control and take less responsibility for their behaviour and its effects (Haslam and Lawrence, 2004).

Therefore, by nudging pregnant smokers towards SSPS through opt-out referral and making the interaction between smokers and HCPs more empowering it is suggested that their health beliefs can be moved towards taking more personal responsibility and being more positive about quitting (NICE, 2010, p44).

Active ingredients

Opt-out referral required high numbers of staff to be trained to babyClear© standards in the new approach. Implementation required the backing of effective performance management and feedback loops to reveal referral compliance levels.

Facilitators	*Barriers*
SSPS with capacity reallocated work to absorb the increase in referrals High levels of integration between organisations Compliance in documentation completion	Slow adopters of change SSPS without capacity struggled to accommodate extra work from referrals Low levels of integration between organisations Non-compliance in documentation completion

Midwives recognised that opting out did nudge women more strongly towards accessing SSPS, which they saw as beneficial, but the option remained for women to choose how to respond. Opt-out referral created an altered demographic of SSPS users:

> *But the difference before was, when we got referrals for pregnant people they'd **wanted** to be referred to the service.*

Interview, Administrator 3, SSS E, 17th July 2014

Another change was the inclusion of smokers and non-smokers, which was reported by the SSS pregnancy specialist in SSS E, as being questioned by midwives. Referral was not considered to be too time consuming:

PT: Only that one little referral slip, which actually is smaller than the other referral,
Interviewer: …what you had before…
PT: …so it's probably easier; it is easier.

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

It led to a more focused and less superficial conversation with pregnant women:

...there was always a component of our booking interview that was about smoking, it was just …I think we probably were a bit superficial before; I'm filling in this referral letter, let them know if you want ... where now, we've moved the goalposts back to us to say, let's put this referral in together and let's do something about it.

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

Summary

1. Change from opt-in to opt-out significantly raised the rate of referral and altered the demographic of clients to SSPS.
2. Some maternity staff were sceptical and resisted, although most went on to successfully and willingly include opt-out referral into their routines.
3. Created significant workload implications for SSPS with reallocation of responsibilities.
4. Compliance in referral form completion, or lack of it, had a major effect on the efficiency of the package; with potential for litigation if non-compliant.
5. Opt-out referral offered a new opportunity for performance management.
6. Benefits of opt-out referral were inconclusive although multiple referrals were seen to be effective in some cases.

Organisations differed in terms of:

1. Use of opt-out for performance management.

Individuals varied in terms of:

1. Level and speed of acceptance of the change to opt-out referral
2. Level of compliance with documentation completion.

Effect of the setting on the hypothesised mechanism

Opt-out referral was not always agreed upon or carried out by frontline staff; performance management and robust feedback loops were required to ensure compliance. The SSPSs experienced the major workload increase, so they were required to respond with sufficient

resources and appropriate services to deliver this mechanism. Variations in context introduced variability regarding the effect of the setting on this mechanism.

Key findings

New systems were successfully created to integrate this change into the referral process, although the rate of adoption varied. This mechanism was reported to support the new discourse and dramatically increase referrals for SS follow-up. This was most marked in areas where maternity staff were confident that effective follow-up systems were in place. This led to a capacity issue in some SSPS, who had to adapt accordingly. Nevertheless, those delivering the SS follow-up did not see the concomitant increased engagement with services that they expected.

7.6.3 Mechanism 3 - Quicker referral

How does increased speed of referral by the midwife to the SSPS increase quit rates?

The evidence:

- Early pregnancy has been found to be a 'teachable moment', that is, when someone is particularly accepting to making a health change (Cooper *et al.*, 2017), and there are better outcomes later in pregnancy when women are first approached in early pregnancy (NICE, 2010, p46).
- The increased number of interventions with the SS message within the babyClear© package is recommended by NICE PH Guidance (2010, p44) to improve outcomes.
- The earlier in pregnancy that a woman is referred, the sooner she will be on the SSPS pathway and the greater number of approaches she will receive.
- Evidence exists that being supported by SSPS increases the probability of a successful quit for a pregnant woman (NICE, 2010, p47; West and McEwen, 2012).

The combination of a 'teachable moment' and systematic, speedier referral was expected to increase quit rates.

Active ingredients

To allow speedy referrals to be made, systems that allowed quick, early referrals were required. Organisations that were well integrated and facilitated feedback loops enabled a faster referral system.

Facilitators	*Barriers*
Early referral, prior to booking-in Some SDMs improved speed / timing of first referral Efficient feedback loops Strong communication channels between organisations	Multiple SSPS SDMs created confusion Some SDMs slowed speed / timing of first referral

The initial referral aimed to be quicker and often earlier in pregnancy than previously. Staff noticed that women's motivation often was not sustained, and that speed and convenience were important to success:

> *For me, my experience is that that immediate follow-up is kind of, that is the key educational moment and to make that behaviour change permanent is about giving somebody the tools that they can go away with.*

Interview, SSS manager 6, Trust A, 18th November 2014

In different SDMs the referral occurred at different time points and involved different providers. Some SDMs tried to monitor pregnant women for CO prior to the booking appointment and make the referral at that point:

> *... if the [maternity care assistant] sees her the minute she hits the GP surgery and says I'm pregnant, then a few days later, brings her in, let's check her demographic details, let's do her height and her weight, sort some bits out, give her all health promotion advice and oh, you smoke, would you like some help with that before you see the midwife.*

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

Geography and location affected service provision and therefore opportunity for early referral. Urban settings had more options than rural ones, including maternity clinics offered in early pregnancy, such as 'early bird' or 'meet & greet' sessions that allowed for earlier referral. All these differences created confusion and, on occasion, introduced delay and challenged compliance. Midwives frequently rang SSPS about cross-boundary issues or were uncertain if women had been contacted by the SSPS following referral, so were left in a quandary when they saw them again:

> *I think the midwives didn't feel confident that women were getting followed up, 'cos there was loads of women going back to the next appointment saying, nobody has contacted me, nobody has contact me.*

Interview, PH Midwife 2, Trust D, 23rd December 2014

Summary

1. The speed of referral and follow-up was important in engaging pregnant smokers with the SSPS.
2. SDMs experienced challenges in complying with the referral process.
3. Inadequate feedback loops left midwives uncertain if smokers had been followed up.

Organisations differed in terms of:

1. Geography and location; urban/rural which affected speed of first referral
2. Speed of referral varied with SDM
3. Efficiency of feedback loops.

Effect of the setting on the hypothesised mechanism

Awareness was required to overcome challenges in terms of system design for speed of referral and to ensure efficient feedback loops. Variations in context introduced variability regarding the effect of the setting on this mechanism.

Key findings

Maternity staff saw their role as referring women as soon as possible and making the most of any teachable moments; but they were dependent on local conditions. A quicker pathway necessitated some system process changes, including further integration of maternity and SiP services. These changes also highlighted some resource implications and gaps in feedback. Some services were able to comply more readily than others.

7.6.4 Mechanism 4 - Total quit

How does making a total quit the only acceptable alternative increase quit rates?

The evidence:

- NICE PH guidance asks HCPs to recommend to pregnant smokers that they quit, not cut down (NICE, 2010, p17; NICE, 2012 - evidence review 2).
- This is based on evidence that reducing gradually makes it less likely someone will quit completely, and more likely they will relapse, compared to an abrupt quit (NICE, 2012 - evidence review 2).

By making a total quit the only acceptable outcome, quit rates are expected to increase.

Active ingredient

To embed the total quit message smokers needed to be empowered to accept and act on the ‘quit completely’ message.

Facilitators	*Barriers*
High level of buy-in to the 'quit completely' message by organisations High level of buy-in to the 'quit completely' message by staff Strong therapeutic relationships Realism about smokers' lives on the part of staff Additional service provision, including multiple SS options	Pregnant women who were living in a demographic where smoking was normalised and personal circumstances were deprived Focus of intervention on personal decision-making rather than social, environmental and systematic constraints Low level of buy-in to the 'quit completely' message by staff

Data supported recognition that cutting down was insufficient, nevertheless, harm reduction was reported as still widely used by pregnant women. Staff reported that persistent smokers may not want to quit but did feel able to cut down:

> *Interviewer: How do you feel about that message, about cutting down is not sufficient, you have actually got to quit?*
> *PT: I have a few and I have actually just had to stop seeing one yesterday, because she still wanted me to give her vouchers, and I said 'I can't. I know you are still smoking.'*
> *'But I've cut down.' 'Yes, I know you've cut down and I am really pleased about that, but we are a quit smoking service'.*

Interview, MCA 1, Trust A, 30th January 2014

The opening phrases used by SSPS advisors, as taught in the training, were seen as important in keeping pregnant smokers on the telephone line.

> *PT: ... When I first make the phone call, I'll say to them, just for example, "Hi [woman's name], NHS Stop Smoking Services, got a referral from your midwife, have you got a couple of minutes to talk to us about it?" … I'll then go on and use, we had motivational interviewing training not so long back and I use them skills as part of it as well and I'll just say, "[Woman's name], how do you feel about stopping smoking?" and then they'll say then, "I want to, but I'm scared I can't."*

Interview, Administrator 4, SSS G, 6th August 2014

Some smokers were honest with staff about their struggles and some were not:

> *In some of them, most of the girls aren't they, they're really open even if they've done really, really well and if they've had that bad week, where*

they've had the odd cigarette, they will admit to it, it's like well I'm not going to lie, and that's good as well.

Group interview, MCA 10, Trust A, 4th February 2014

And they'll say oh I've quit, and you can hear them, but you've got to just take it as the truth because you can't say I can hear you smoking. You can't call them liars and you know truthfully that they haven't quit.

Interview, Administrator 4, SSS G, 6th August 2014

Pregnant smokers would return repeatedly to the SSPS but only some succeeded in quitting. There were alternative supports that maternity staff could draw on in recognition of the need for a holistic approach which, bearing in mind their likely circumstances, might help women gain sufficient emotional stability to attempt to quit. Women themselves had seen the impact of quitting in their own lives:

...well what happened in between then and then [different pregnancies] and she said I stopped smoking - and she knew. So, you can get that message across, and they can see the difference.

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

Although numbers were small, staff reported some successes:

Some cut down but the majority that we see, touch wood, they do quit.

Interview, MCA 1, Trust A, 30th January 2014

I've managed to get, over the last I think seven months, there's been five of them come through and three of them have quit. One of them was a little bit hitty-missy but I've got two that are in week ten; they've got two more weeks to go, so they'll be clear.

Paired interview, Community Outreach Worker 1, SSS G, 18th December 2014

Some staff expressed how they had changed the advice they gave in line with the recommendations from NICE PH Guidance (2010):

PT: Yeah, I think in the past I would have praised somebody for cutting down but it's not enough.
PT: No.
PT: I wouldn't even comment on them cutting down, I just focus on stopping now.

Paired interview, RPT Midwives 12 & 13, Trust A, 27th January 2014

Some staff recognised the importance of quitting, not only to improve baby's weight, but all the other health issues as well and explained the reasons to pregnant smokers:

> *...it's everything else that goes around it, the miscarriage, the risk of pre-term labour, the baby that's not so mature and ends up in special care baby unit or years down the line, the baby that has issues with its health.*

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

While others were reported as having reservations about complete quitting:

> *I think there are some midwives who still don't think it is important and there will always be those there, that don't believe it really affects the placenta to the degree it can.*

Interview, Pregnancy Specialist SS advisor 2, SSS C, 6th May 2014

There was unease amongst some midwives about challenging smoking behaviour, because typically, this group who continued to smoke, lived among other smokers and had complex needs. Staff believed that, fundamental to successful support with any pregnant woman was a functional, therapeutic relationship and that challenging smoking behaviour may threaten this relationship. There needed to be trust on both sides for the relationship to function well:

> *Because they have got to trust you, haven't they? And you have got to be very approachable, because you have got to say, 'I am not going to take any ….'. If you get someone blowing in 'I haven't had a smoke.' 'Well, come on now, tell us the truth, now', and then they will. Then they will go 'well.' And some of them are a bit disappointed because they don't want to let you down. They will go 'I've let you down this week'. I will say 'well you haven't let me down, but you have let yourself down', and so you do get a bit of that as well*.

Interview, MCA 3, Trust A, 7th March 2014

In some places, CO monitoring and discussion of smoking was reported as becoming normalised and offering less threat to the therapeutic relationship:

> *Interviewer: I know one of the big issues was, about before this, for midwives, was about the breaking down of the relationship with the patient. Do you feel that is an issue?*
> *PT: No, I don't think it is anymore. They are classing it as this is part of the routine antenatal care now.*

Interview, Pregnancy Specialist SS advisor 2, SSS C, 6th May 2014

Some staff thought that maternity staff's involvement should go further:

> *...we're more or less saying you know we'd like you to stop but you don't have to and again I think, and again I'm going to be more controversial now, you know with people who abuse substances we'll make child protection referrals, yet we let women harm their babies through smoking and we don't, you know there's different standards that we have but maybe that's right. I don't think so.*

Interview, Senior Manager 8, Trust B, 15th September 2014

Summary

1. Although midwives referred smokers for support with a variety of circumstances, as well as to SSPS, the approach to changing smoking behaviour was primarily focused on altering personal decisions.
2. Some smokers were enabled to quit who were unlikely to have done so without the extra support.
3. Level of staff buy-in to the 'quit completely' message was mixed, with some completely in favour and a minority remaining hesitant.

Organisations differed in terms of:

1. Demographic of the patients they cared for
2. Holistic/alternative service provision available
3. The degree they supported the 'quit completely' message.

Individuals varied in terms of:

1. How effectively they managed the interface between the message and the reality of smokers' lives
2. Their ability to develop a strong therapeutic relationship
3. Belief and buy-in to the 'quit completely' message.

Effect of the setting on the hypothesised mechanism

It was found that the intervention did not threaten therapeutic relationships. When staff experienced success in seeing women quit, they were enthused. Nevertheless, this target population lived lives where smoking was systematically entrenched; implementing an intervention that focused on attending to their personal decision-making created tension and was sometimes experienced as a potential threat to the therapeutic relationship, undermining staff support for the mechanism. Variations in context introduced variability regarding the effect of the setting on this mechanism.

Key findings

This was a new approach for some maternity staff. Analysis found that maternity staff reported themselves and pregnant women as often being conflicted over this mechanism. Belief in cutting down vs total quit, as the goal, related to perceptions of achievability by both service providers and users. Quitting completely for some women was seen by themselves and some staff as unrealistic; although other staff were convinced of its achievability.

7.6.5 Mechanism 5 - Quicker follow-up

How do increased speed/strict timeframes within which contact is pursued at each point by the SSPS increase quit rates?

The evidence:

- Evidence regarding the timing of teachable moments, the importance of rapport and relationship with HCPs offering an empowering approach, frequent interactions with HCPs and opportunities to hear the SS message repeated, point towards a pathway with fast and strict timeframes for contact (NICE, 2010, p44, 46; NICE, 2017, p7). (Also see Mechanisms 3 and 4).

Therefore, timing and repeated interactions with HCPs appear to be significant in pregnant smokers' decision-making around quitting.

Active ingredient

Restructuring and resourcing of systems was necessary to enable quicker timeframes to support an increase in quit rates.

Facilitators	*Barriers*
A supportive philosophy behind the SDM that gave SS priority and accepted that this group of smokers needed additional support to quit Pre-existing SDMs that required less modification to comply with the package Senior managers who facilitated changes to comply with the new package Making SS support easily accessible and convenient to pregnant smokers	An unsupportive philosophy behind the SDM that did not give SS priority and did not accept that this group of smokers needed additional support to quit Pre-existing SDMs that required greater modification to comply with the package Organisations that were already under pressure e.g. from restructuring, job losses, feeling undervalued, were in a weaker position to deal with the extra pressure from implementing the new package

	Senior managers who did not facilitate changes to comply with the new package Making SS support comparatively less easily accessible and convenient to pregnant smokers

Speed was seen by staff as an important mechanism to engage women:

> *... like striking while the iron's hot as sometimes I can get a better response from them because they're like oh, G**, that's fast, yeah, it's something I want to do, or by the time they've had a chance to think about it, if I give them too much time to think about it and they've now decided they don't want to quit...*

Interview, Administrator 4, SSS G, 6th August 2014

Many factors affected timeframes e.g. the quality of data management tools, SSPS systems that sent confusing telephone caller number displays, insufficient levels of consent from women documented by maternity services:

> *That lady has a miscarriage because she hasn't stopped smoking but wanted to stop, nobody's contacted her, in theory, because we've had no permission to leave her a voicemail. Our number isn't our number so whatever comes through on your 'phone isn't the Stop Smoking Service, we're all linked to the hospital switchboard. So, they go back to the hospital from [Trust G], they panic; they don't know where the phone call has come from.*

Interview, Administrator 4, SSS G, 6th August 2014

The SDM affected timeframes; roles and intervention varied e.g. a public health nurse made the call, or alternatively MCAs intervened. The increased volume and quicker timeframes put SSPS staff under pressure:

> *PT 124: … we were struggling to keep up with people.*
> *PT 123: We couldn't keep up, it was impossible to keep up.*

Paired interview, SSS administrators 5 & 6, 9th December 2014

As did the offer of home visits, especially in more rural areas:

> *They thought they were just, we could just quickly do home visits and get there in five minutes. Some of ours are an hour and 20 minutes away to do a home visit. And that sort of thing wasn't taken into account, the*

differentials between, like I said, [City 1] service, which is pretty tight, and [Locality 5].

Interview, Administrator 3, SSS E, 17th July 2014

Speed of access depended on the interplay between these factors and women's circumstances i.e. smokers' home address and transport arrangements. There was an element of serendipity as to how well this might work out:

I mean yesterday there was a lady and she lives in [small town 22], which is sort of I mean miles, but it's between [small town 18] and [small town 17] in the middle of nowhere. So, she would have to go to [small town 18] or [small town 17] for our clinics or to her practice. But practice nurses, unless they're really up and running...if, you know, for the odd one we might get, and we sort of liaise. But as I was covering the north yesterday, I just said I would see her at home on the way between the two and then arranged to see her again at home, 'cause we're there once a week or so. So that's the way it would work for that.

Interview, Specialist Stop Smoking Advisor 3, SSS E, 17th July 2014

Some women were quick to accept the opportunity for support to quit but others hesitated. However, the SDM in some Trusts ensured they would be approached again shortly. For speed of contact relating to the RPT, see mechanism 8.

Summary

1. SSPSs succeeded in creating pathways whereby those referred were contacted within quicker timeframes.
2. The pathways to contact and access NRT varied in each SSPS; therefore, women were offered different opportunities.
3. New pathways created extra pressure on staff (increased volume of referrals, offer of more follow-up options, old data management processes).
4. Accessing NRT required commitment by the smoker to many steps, some of which might be inconvenient, which slowed the process down.

Organisations differed in terms of:

1. Underlying SDMs and how they were altered to accommodate quicker timeframes for contact
2. The ways they pursued smokers who were resistant to engagement
3. Their beliefs about how to support pregnant women effectively to quit smoking
4. The resources they made available to meet package timeframes.

Individuals varied in terms of:

1. Their attitude towards changing practice to implement the package within system constraints.

Effect of the setting on the hypothesised mechanism

The systems needed to be restructured to comply with the package and provide quicker timeframes. This was achievable, but at a cost. For many services this did not fit with their SSPS structures and/or they were not able to provide the extra resources required to introduce or sustain the necessary changes. Variations in context introduced variability regarding the effect of the setting on this mechanism.

Key findings

Pregnant women were reported to be more open and likely to engage with the SSPS soon after seeing their midwife. However, midwives were dependent on systems being available to women that routinely offered this enhanced service. SSPSs were required to change to meet these new demands, which were reported to incur resource and opportunity costs.

7.6.6 Mechanism 6 - New discourse

How does changing the language/tone of the SC message improve outcomes?

The evidence:

- Pregnant smokers can find themselves stigmatised and held responsible for the health of their growing baby (Lupton, 2012).
- Some women, especially those living in socioeconomically disadvantaged circumstances, who are also more likely to smoke, be more nicotine dependent and find it harder to quit, may find themselves in a situation of feeling judged or pushed to conform; a situation they want to avoid (Lupton, 2012; PHE, 2015b; NICE, 2017, p16).
- NICE PH Guidance (2010) recommends a caring, empathetic approach to combat women's fears of failure to quit and stigmatisation over their smoking an approach that will empower them to feel able to succeed in quitting (p44, 49).

How staff speak to pregnant smokers appears to be pivotal in terms of women's responses to being challenged; a non-confrontational exchange is important.

Active ingredient

Maternity and SSPS staff who were trained in motivational interviewing and accepted the new discourse were more likely to use it to engage successfully with women to challenge their smoking habits.

Facilitators	*Barriers*
Motivational interviewing is already used and accepted by midwives Fully trained in babyClear© approach Personal qualities of HCP	Staff unable to access babyClear© training Personal qualities of HCP

The training offered staff a specific new discourse which built on their motivational interviewing skills. This was seen as a key to success:

> *...we can give her nicotine replacement therapy and support the physical addiction that way, but what we absolutely know from the research is that it's the counselling that's key in all of this as well. And the only way of doing that is equipping the staff to be able to talk to the women, use those open-ended questions, challenge their behaviour, sow that seed, not tell people what to do, not give them advice, but help them develop coping strategies and ways of living without cigarettes.*

Interview, Lead Trainer, 24th November 2014

Data show that the babyClear© discourse was characterised by speaking to pregnant smokers with empathy, reassurance, encouragement, affirmation, a sense of mission and passion. In addition, to build motivation, staff were required to adapt the style and content of a clinical encounter to the woman:

> *...Some women you can give them these hard facts. Other women you have to soft soap them a little bit, you know; you can't go telling everybody the same information in the same way*.

Interview, Community Midwife, team lead 4, Trust A, 4th February 2014

Senior staff were confident that confronting women about their smoking need not be received as a threat. In some SDMs this challenge fell more on the MCAs than the midwives:

> *The relationships these girls have got with the women is, when you hear them talk about it, they get such a thrill, the [MCAs], in developing that relationship and when there's a success at the end they're absolutely delighted with that and the development of that relationship's massive*.

Interview, Senior Manager 1, Trust A, 5th August 2014

More analysis on the use of motivational interviewing can be found relating to staff training, under mechanism 10 (see 7.6.10).

Summary

1. How pregnant smokers were approached by staff was key to a successful quit.
2. Motivational interviewing has been previously employed in SS advice and was used in the training, alongside a new discourse, to apply the intervention.
3. The new discourse was characterised by empowerment and support to quit.
4. Different roles within maternity and stop smoking in pregnancy services were required to use the new discourse.

Individual staff varied in terms of:

1. Personal qualities that fitted them for the role
2. Preparedness to change their approach.

Effect of the setting on the hypothesised mechanism

This mechanism was largely reported as successful and most staff integrated the training into their own practice. Variation in individual buy-in and ability would be the main factors that would influence the effect of this mechanism.

Key finding

Maternity and stop smoking in pregnancy services staff were provided with a new language for discussing smoking with pregnant women. Staff reported that it built on existing professional skills and addressed midwives fears over damaging their relationship with women. It offered staff an effective way to express care and empathy and reach more women. Staff thought that it encouraged women to believe they could succeed in quitting.

7.6.7 Mechanism 7 - More frequent follow-up

How does increased contact with pregnant smokers by the SSPS increase quit rates?

The evidence:

- Evidence accepted by NICE found that increased contact as part of a package of measures was more effective than less intensive support (2010, p47).

Intensive support has been recognised as an important element of a successful stop smoking in pregnancy pathway.

Active ingredients

Increased contact was enabled in SSPS with resources and systems that flexed with the pregnant women and in maternity and stop smoking services that were well integrated and operated robust feedback loops.

Facilitators	*Barriers*
Opt-out referral system Multiple attempts at contact Making contact convenient to the smoker Making re-engagement easy Extended support beyond statutory requirements Ensuring maternity and stop smoking in pregnancy services communicated to one another and remained up-to-date about the smoker's progress	Staff not fully engaging with the intervention Lack of flexibility within SDMs to respond to smokers' preferences Resources channelled away from SSPS Incomplete feedback loops Lack of prioritisation of SSPS

Increased interaction between women and the SSPS was seen by staff as important in supporting quit attempts:

> *...if you've got support there or someone coming out going to do the CO reading you'd definitely think 'oh right so and so is coming next week so I'll keep going with this', where if there's no support there they just slip back into the habit again*.

Group interview, MCA 11, Trust A, 4th February 2014

Extra time and resource was focused on increasing contact with pregnant smokers. In some SSPS the pathway was entirely new and sometimes still being decided, even after babyClear© training had commenced. More options were offered e.g. home visits (see 7.4.3), different ideas were tried to increase contact e.g. weekend telephone support or blending SSPS support with other community services. Following the introduction of universal CO monitoring and opt-out referral, SSPS clinics did not see the rise in numbers they expected:

> *…we opened 2 extra pilot clinics, because we thought, right, we need this for the demand and we've actually...there were hardly any that attended.*

Interview, SSS manager 4, SSS D, 21st January 2014

Neither did pharmacies, which were the SSPS provider in some SDMs:

> *…when I was going around [Large town 1] the last time nothing at all I could see that was coming from any referrals from babyClear© to any pharmacies in [Large town 2].*

Interview, Lead Pharmacist, SSS B, F & G, 18th September 2014

RPT clinics were smaller than expected, although in part this might have been due to taking time to efficiently channel smokers into the clinics. Resistance to engagement, reflected in low uptake of services, caused delay in starting a quit attempt. Although SSPSs contacted women within the new timeframe, the response was often negative:

> *...you leave messages and nine times out of ten they won't ring you back, and then the letter comes out. So, it is quite a lot of time I've spent, about an hour and a half this morning, just making phone calls to pregnant people, trying to catch them in.*

Interview, Administrator 3, SSS E, 17th July 2014

Many women did not attend their appointments or cancelled at the last minute. Attendance was too low to justify the expense and clinics had to close:

> *...You know, the take-up wasn't consistently enough to warrant us down there, there's not that amount of resource, to be honest.*

Interview, Specialist Stop Smoking Advisor 3, SSS E, 17th July 2014

It was noted that women made themselves unavailable after the initial appointment:

> *...when you actually go to their houses, they might be in the first time, but I would think about 70% of them aren't in the second time.*

Interview, Pregnancy Specialist SS advisor 2, SSS C, 6th May 2014

Re-referral during the pregnancy was encouraged if a woman had not engaged at all or wanted to re-engage with the SSPS:

> *…sometimes it takes them more than one attempt to even get into quitting. But you find, we have a few ladies, we have seen them once, a few weeks down the line, they will think 'oh I really want to see someone again' and they will ring us up, and we will see them. They won't quit that time, third or fourth time they might quit, but as long as you are willing to keep trying…*

Interview, MCA 1, Trust A, 30th January 2014

Feedback loops were necessary to ensure that contact was increased appropriately, but the necessary resources were not always available:

> *Well it's not the cost, I think the greater, it's not the greater cost of not, in having to do it without Quit Manager®. I think it's the fact that the process isn't efficient without it. It's very difficult to be efficient and to complete it without having the facilities to do it.*

Paired interview, Administrator 5, SSS H, 9th December 2014

When feedback was not established or failed, midwives' confidence in the SSPS faltered:

> *When we moved over to the new service, there wasn't any follow-up anyway. So, I think the midwives suddenly had to go from an old service that they didn't feel was like doing very well, to suddenly having to send all these women to pharmacy because that was the best thing we could do, because we didn't have anything else.*

Interview, PH Midwife 2, Trust D, 23rd December 2014

There was recognition that staff relationships that enabled feedback loops took time to establish:

> *I think once all the midwives understand what our role is, because, you know, some of them are getting, little meetings here, little meetings there, and then they realise that we're actually part of the, not the booking in but sort of the first scan appointment.*

Paired interview, Community Outreach Worker 1, SSS G, 18th December 2014

Amidst this context of fluctuation, integrated services encouraged unbroken links and successful contacts:

> *…that for me is why I'm very much keen to get kind of like the babyClear© element of Quit Manager® on board so that it is robust, so that we've got the data there, you know. I can actually feed back to Maternity Services and increase their confidence in the service, you know, as well as feeding back to the level two providers [generalist stop smoking advisors], you know, and giving them updates in terms of their own performance in comparison to other level two providers' performance. But, you know, to feed back for Maternity Services on the outcome of referrals so that when they go and have their next appointment with the pregnant lady that actually they can bring up the topic of smoking again and offer that referral if required.*

Interview, SSS manager 6, Trust D, 18th November 2014

Summary

1. Progress was made towards implementing the babyClear© package, including increased contact between women and the SSPS, through greater inclusivity, raising the standard and increasing compliance.
2. Lower increase in uptake of services occurred, compared with the expectation of SSPS, following the introduction of babyClear©.
3. Pregnant smokers were often resistant to SSPSs' attempts to make contact; much organisational resource was absorbed trying to make contact and enable appointments.
4. Measures to improve levels of engagement were introduced, including greater support from the administrative offices, more options and greater capacity for follow-up (especially home visits), an open-door approach to re-engagement and higher levels of support throughout and beyond the standard government recommendations.
5. Re-referral and feedback loops were systematic actions introduced to increase the effectiveness of contacting smokers.

Organisations differed in terms of:

1. When/ how and with whom contact was made
2. How they addressed issues of low uptake
3. The resources they made available to encourage engagement
4. How quickly and thoroughly systems were introduced.

Individuals varied in terms of:

1. The effort they put in to overcome barriers e.g. smokers' resistance to engagement, completing feedback loops.

Effect of the setting on the hypothesised mechanisms

Systems were restructured to increase contact and to monitor progress through feedback loops. This was more demanding for some systems than others. Increasing contact was far harder than anticipated and absorbed extensive resource for, what appeared to be, little return. Variations in context introduced variability regarding the effect of the setting on this mechanism.

Key finding

Staff reported that women felt more cared for and were more inclined to take personal responsibility for their smoking behaviour when they met more frequently with HCPs. There were resource implications, especially for SSPS, to provide these options, which were not

available in all locations. Nor were these opportunities always taken up by women. System changes were also required to feed back timely monitoring information and these processes could be unreliable.

7.6.8 Mechanism 8 - Risk Perception Tool

How does introducing the RPT increase quit rates?

The evidence:

- Evidence suggests that coming from a position of care and concern (see mechanism 4; NICE, 2010, p44, 49), yet presenting the risk visually and strongly, in ways that force pregnant smokers to face what they are doing to their unborn baby (see mechanism 1; Hoek *et al.*, 2014; Sloan *et al.*, 2016) gives some of them the impetus they need to change (Peters, Ruiter and Kok, 2013).

This is not a recommendation from NICE PH Guidance (2010) and the trial evidence for its effectiveness does not exist at present; however, it is hoped that the process evaluation will be able to contribute some qualitative evidence.

Active ingredients

Believing in the effectiveness of the RPT and thinking creatively about how to implement this tool were thought to make it more likely that quit rates would increase.

Facilitators	*Barriers*
Systems where midwives were already present in dating scan clinics Maternity and SSPS that were already working together Organisations that embraced change; flexible and adaptable Senior managers who were proactive and prioritised SS by creating opportunities, enthusing their staff, overcoming barriers, providing extra resource and supporting the changes Clinical staff who believed in and enthusiastically delivered the RPT	Systems with no midwives in dating scan clinics New SSPS SDMs without pre-existing links into maternity services and/or did not have established SS pathways for pregnant smokers Organisations that resisted change Senior managers who were reactive in terms of driving the implementation forward and/or left it to others to try to create opportunities and bring about the changes Clinical staff who were slow to adopt the intervention into practice.

The powerful way the RPT communicated the SS message was recognised:

> *I certainly think I'm getting better at it and knowing what works with the women and I usually find if you show them how the baby's heartbeat faster that's quite powerful and obviously the cord, squeezing the cord.*

Interview, PH Midwife 1, Trust B, 21st March 2014

The necessity of delivering the SS message in such a shocking way was accepted:

> *…talking to them in more depth and shocking them, probably, is what you've got to do, isn't it really? And I don't feel, I'm just trying to think, I don't feel guilty or anything talking to them about it.*

Interview, PH Midwife 1, Trust B, 21st March 2014

Senior managers were persuaded of its value:

> *I think it's probably what they needed. Visualisation is so much more powerful than just a discussion and to see it, I think that's that massive impact and that sort of tummy blow, oh my God! This is what I'm doing. The use of the dolls and the placenta and the smoke, all of that, that visualisation, the talking through and that understanding has so much more of an impact than just sitting talking to somebody and telling them about the risks. This is demonstrating the risk.*

Interview, Senior Manager 1, Trust A, 5th August 2014

There was concern on the part of some midwives about delivering the SS message in this way but eventually they were persuaded of its value:

> *…there was some anxiety at the beginning, not so much about the babyClear© part but the risk perception part, about can we really do this to women but actually yes, we can because it focuses them in on the reality of what they're doing to their babies and themselves.*

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

There was scepticism and speculation as to how much difference the RPT might make:

> *…we'll also be able to see whether or not, a lot of those who didn't engage the first time, after they've had the risk perception intervention, engage a second time and out of those how many go on to be quits.*

Interview, SSS manager 4, SSS D, 21st January 2014

> *I think I was probably hoping for better results from it than what we have got, and then you question yourself don't you? Is it the way that I am delivering it? Is that why these women aren't taking it up?*

Interview, RPT/Community Midwife 10, Trust D, 23rd December 2014

Staff favoured the timing of the RPT within the maternal pathway and considered that, logistically, coinciding it with the dating scan worked well:

> *Interviewer: So, you think the timing of the risk perception tool at the dating scan is actually working?*
> *All: Oh god yeah.*
> *PT: It's brilliant.*

Group interview, MCA 4, Trust A, 4th February 2014

There were considerable delays in every Trust related to introducing the RPT, due to a variety of causes, including identifying staff to deliver it, accessing training and running the software. In some areas the situation improved and the RPT clinics were running smoothly:

> *…the logistics of putting a new service in with no extra staff or hours was always going to be difficult and so we've had to be creative to be able to manage it and we have.*

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

In many areas there were ongoing issues regarding funnelling smokers into RPT clinics and training sufficient numbers of staff to deliver it:

> *…they have their scan at [RP intervention site 13], where nobody does risk perception tool, so they slip through the net a little there.*

Group interview, PH Nurse 1, SSS J, 8th October 2014

> *We're not seeing 100% of smokers at this point, but we thought we'd rather start and see as many as we can.*

Paired interview, RPT Midwife 12, Trust F, 15th January 2015

> *But if you've got midwives and healthcare assistants to deliver the risk perception tool and there's nobody coming through, they're sitting with no patients.*

Interview, Senior Manager 1, Trust A, 5th August 2014

The requirement for a midwife to give the RPT was a significant barrier to implementation:

> *That was probably our biggest challenge, to reconfigure clinics to be able to fit that in, because it wasn't something that we had, and we didn't have midwives, specifically in those particular clinics…*

Interview, Senior Manager 8, Trust B, 15th September 2014

But because of the quite – I don't want to call it aggressive – but quite graphic, some of the information that they're given, they wanted it to be led by the nurse in the nurse setting, because they show them some quite difficult pictures about babies and placentas and stuff. So, they wanted that done there, and they refer into us afterwards once they've decided they will quit.

Paired interview, Pharmacist, SSS B, F & G, 6th November 2014

Staff reported that pregnant smokers generally perceived the RPT positively:

I've had a lot of feedback from women who have given up and are pleased…

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

Yeah, and amazingly, better than I thought. I was a bit worried about doing it, when I went on the training day I was what, this really can't do this, but I'm actually enjoying it and the reception has been quite good. People have been, some have even thanked me, so it's been good.

Paired interview, RPT Midwife 12, Trust F, 15th January 2015

Other staff reported isolated, negative responses by women to the RPT:

…and a couple, just a couple who fed back to say that they didn't appreciate the scaremongering and that made their resolve to quit, it didn't alter it one jot; and they carried on, it made them more stressed and so they smoked more. They obviously didn't get it, doesn't matter how much and how you approach, for some people you're not going to get there, there's always been, going to be the one that doesn't want to do it and won't do it.

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

Different organisations designed different SDMs to follow up the smoker after the RPT and various approaches were introduced, tested and tweaked; appointments made directly, or smokers were seen immediately after the RPT, before leaving the hospital. It was described as unethical if suitable follow-up was not made available:

We're working with the risk perception tool. You're bringing a woman in, you're telling them that there's a real issue with the level of CO in their baby, we're giving them products to go out, but then there's no support mechanism being able to be offered outside of that. And it worries me a little bit ethically, that it's a little bit cruel, that we're frightening women saying, you know, you really need to stop smoking, look at the health risks associated with this, but then there's nobody at the other end picking it up and giving them the support. And we've only got limited capacity.

Interview, Senior Manager 1, Trust A, 5th August 2014

Providing RPT follow-up was time consuming, with low attendance but high investment on the part of SSPSs, thus creating opportunity costs:

> *… my pregnancy adviser is … now spending two days specifically on this intervention post scan. So, I have had to pull her out of other clinics. So, the women who are hardest to influence are getting the Rolls Royce treatment … So, my pregnancy advisor's main focus now is on these women that are so hard to reach, and it is an awful lot of effort to put in for a few outcomes, but it could be that those are the most important outcomes that justify the effort, but for me the jury is still out on that.*

Interview, SSS manager 1, SSS C, 30th June 2014

Summary

1. Staff believed that the RPT delivered a powerful, visual message which differed significantly from usual care.
2. Senior managers supported the idea of the RPT, but some frontline staff needed persuading, through seeing it working, before they were reassured of its benefits, and that the benefits outweighed any threat to the therapeutic relationship.
3. It was accepted that the dating scan was an effective time to deliver the RPT.
4. Barriers to implementing the RPT, whereby the specialist staff and equipment were present with the smoker simultaneously, were manifold.
5. Staff reported that most pregnant smokers accepted the message of the RPT.
6. SSPSs attempted to offer immediate follow-up after the RPT within a variety of SDMs.

Organisations differed in terms of:

1. Existing systems in place
2. Readiness to adapt for the implementation
3. SDMs developed to provide the RPT.

Individuals varied in terms of:

1. Ways in which staff adapted the RPT to the smoker
2. Smokers' responses to the RPT
3. Views on acceptability and consistency with professional values
4. Views on effectiveness of the RPT
5. Views on the necessity of a midwife delivering the RPT.

Effect of the setting on the hypothesised mechanism
In some settings the RPT was established and experienced as effective. However, in all settings it required significant system restructuring to implement. This involved identifying appropriate staff and equipment to deliver it, which usually involved a cost, at a time of cutbacks. Variations in context introduced variability regarding the effect of the setting on this mechanism.

Key findings
Maternity staff were largely supportive of the RPT and came to believe in it, where it had been implemented, but initially systems were not in place to deliver it properly. Organisations were not configured in ways that would lead to effective delivery to pregnant smokers. These logistical challenges obstructed implementation and creative solutions were required to overcome them.

7.6.9 Mechanism 9 - Multiple follow-up options

How does offering a variety of accessible SC follow up options increase quit rates?
The evidence:

- NICE PH Guidance (2010, p11; 2017, p7) evidence recommends a variety of options, locations and settings, including home visits.

This multiplicity of options aims to reduce barriers to engagement by making SSPS as accessible as possible, as a way of increasing quit rates.

All areas offered a variety of options, some more, others less. Different areas offered different combinations (see Chapter 6).

Summary

1. It was not possible to be clear about the effect on quit rates of specific or collective follow up options.

Organisations differed in terms of:
What they provided by way of follow-up support.

Effect of the setting on the hypothesised mechanism
Variations in context introduced variability regarding the effect of the different options within each setting for this mechanism.

Key finding

Multiple options were recommended but a picture of mixed provision emerged with uncertainty amongst staff as to the effectiveness and/or cost-effectiveness of any option or group of options.

7.6.10 Mechanism 10 - Staff training

The evidence:

Effective training is known to improve expected outcomes (NICE, 2010; 2017). To be effective it must be fit-for-purpose and support staff to become more proficient in their roles (NICE, 2010).

The babyClear© training programme is outlined in 5.3.1; however, its effectiveness is not yet known (Fendall *et al.*, 2012).

a. How does the staff training increase quit rates?

It is anticipated that by enabling staff to implement the hypothesised mechanisms proficiently, quit rates will increase.

Active ingredient

Maternity and SSPS staff who were well-suited to the work, with an adaptable approach and training in motivational interviewing, were more likely to increase quit rates i.e. training in mechanism 6 – the new discourse, which has the same facilitators and barriers.

Facilitators	*Barriers*
Motivational interviewing is already used and accepted by midwives Fully trained workforce Personal qualities of HCP	Staff unable to access training Personal qualities of HCP

The training enabled staff to implement the intervention, in so far as it was within their remit. Beyond adhering to systems (see Mechanism 11), motivational interviewing and the new discourse were the main ways that the training was perceived to equip staff to increase quit rates. Motivational interviewing was already well-established as an appropriate approach; it was taught in generic SS advisor training. BabyClear© training built upon this foundation. Amongst pregnant smokers it was recognised by staff that there were those who were not keen to quit, and the training equipped them to advise these women to do so, due to their pregnancy.

Motivational interviewing helped staff to engage with these smokers:

> *So, the motivation levels going into the quit attempt are very different and the reasons for motivation are different, so we know that they don't necessarily quit in such high numbers as the general population*.

Interview, Fresh Specialist 1, Fresh NE, 17th June 2014

> *...we know that pregnancy smokers are a particularly difficult cohort to get quits, because somebody will be there being corralled into quitting at a time when maybe they don't feel ready to do so, but everybody is telling them that they should do so*.

Interview, Lead Trainer, 24th November 2014

Summary

1. Motivational interviewing is a well-established collection of techniques to encourage changes in behaviour.
2. Motivational interviewing has been previously employed in SS advice and was used in the training to apply the intervention.
3. Many reluctant quitters were now being referred to SSPS and motivational interviewing was used to engage them.
4. Motivational interviewing was used to strengthen the therapeutic relationship and to adapt and tailor the clinical encounter skilfully.

Individual staff varied in terms of:

1. Personal qualities that fitted them for the role
2. Preparedness to change their approach.

Effect of the setting on the hypothesised mechanism

This mechanism was largely reported as successful and most staff integrated the training into their own practice. Variation in individual buy-in and ability would be the main effect on the mechanism.

b. How does increased prioritisation of the SC message increase quit rates?

It is anticipated that through prioritisation of the activities within the pathway it will become normalised, the mechanisms will come into operation and the quit rates will increase.

Active ingredient

Systematic prioritisation of SS training by senior staff so that frontline staff were equipped with the new discourse created opportunities for increasing the quit rate.

Facilitators	*Barriers*
Systematic prioritisation	Insufficient senior support for the training
Fully trained workforce	Staff unable to access training
Personal qualities of HCP	Personal qualities of HCP
Smoker feels ready to quit	Smoker does not feel ready to quit

It was reported that many midwives were uncomfortable about exploring smoking with pregnant smokers (NICE, 2010, p17, 22). By training and equipping them to overcome these uncertainties, SS conversations can happen more frequently and effectively, as per the recommended pathway (NICE, 2010; 2017).

Training for HCPs in the babyClear© package

Training was conducted for all staff who would be implementing a part of the package, thus raising awareness of smoking as an issue and providing a new discourse.

Prioritisation

Training systematically encouraged prioritisation of speaking to pregnant women about smoking, although there were many hindrances. Centralising training was intended to reduce the number of sessions required but this created cover issues for staff, some of whom struggled to be released at the relevant times and for sufficient time to travel to venues. Extra 'mop-up' sessions had to be organised to increase the numbers of staff who had received training. To some extent this was due to the large geographical area and the nature of their work but sometimes it was due to lack of senior support within the Trust:

> *It's even like the babyClear© training, for example, when it was first being done we were trying to incorporate everybody. Now they knew that was coming, they'd been given the dates for it and I kept saying to the community nurses when I saw them, oh, which of the training are you going on to do the babyClear©? And they were, what training, don't know nothing about it. Didn't know nothing about it, you know. I'm saying, well, you'd have had an email from... No, what's that? And they were going... and nobody was like, you know. And it got to the stage where it was like you've got to go on this training a week before. You know, some of them were finding out a week before and they were saying, well, we can't go, you know, so-and-so's off on holiday and there's no way we can go. And so, you've got this sort of hotchpotch and that kind of went on*.

Interview, Specialist Stop Smoking Advisor 3, SSS E, 17th July 2014

Usual Care, Service Systems Alterations

Usual care was the backdrop into which the intervention was being placed. Training was carried out with staff for whom this would be the norm. The trainers expected usual care to conform to a standard delivery model, however it varied widely between localities and organisations, as did take-up of local resourcing and enabling of change (see Chapter 6). Therefore, it was not possible to standardise how the intervention was introduced and implemented; the alterations required to bring in the babyClear© package, although intended to be the same, and to produce the same service, were different:

> *I'm not sure that if you went into babyClear© in one Trust it would look exactly the same as it does in another.*

Interview, Fresh Specialist 1, Fresh NE, 17th June 2014

Summary

1. Training was provided but it required systematic prioritisation by senior staff to enable comprehensive numbers of staff to be trained and awareness of the SS message to be raised.

Organisations differed in terms of:

1. Levels of systematic prioritisation of the intervention
2. Usual care which led to variance in context for the implementation of the intervention.

Effect of the setting on the hypothesised mechanism

The training itself was standardised and assisted staff to prioritise SS messages but accessing and applying the training could be challenging. Variations in context introduced variability regarding the effect of the setting on this mechanism.

c. How does routinising CO monitoring increase quit rates?

Evidence used to develop NICE PH Guidance suggests that regular CO monitoring assists smokers in quitting (2010, p12).

Active ingredient

When senior support for ensuring training and systems for universal CO monitoring, performance management and feedback were put in place an increase in quit rates was supported.

Facilitators	*Barriers*
Tried and tested NICE PH Guidance (2010; 2013a) Evidence-based measure of CO Trusts that mandated SS update training Universal, routine CO monitoring implemented Robust feedback loops	Variable application of the package SS training non-statutory Varied frequency of CO monitoring Different information governance rulings about handling of non-smokers' data Variable compliance with universal, routine CO monitoring Incomplete feedback loops

CO monitoring was already established to varying degrees; however, the intervention underlined its importance and encouraged buy-in. It offered a positive way for midwives to discuss changing smoking behaviour with pregnant women:

> *I mean I didn't have a problem with talking about smoking, I don't think, to pregnant women, but I definitely do feel that it is better talking about carbon monoxide readings and discussing it from that point of view, rather than saying it is smoking. It has sort of changed the focus a little bit.*

Interview, RPT/Community Midwife 10, Trust D, 23rd December 2014

Additional ways in which it appeared to improve outcomes included repeated CO monitoring, SSPS contact and re-referring which sometimes facilitated women attempting a quit later in pregnancy.

Compliance levels by organisations varied. Managing staff performance was possible once the expectation for universal monitoring was established; this allowed any gaps to be identified and dealt with and became the responsibility of the babyClear© lead:

> *… in terms of monitoring performance, to make sure that midwives are actually following the protocol and delivering what they should be delivering and if there is any kind of outliers where we are getting, for example, more opt-outs in certain areas, that we can look at why that is and put support there for maternity services to turn that round.*

Group interview, SSS Specialist Advisor 1, Trust A, 31st January 2014

HCPs saw it as an effective, motivating tool and reported that women often reacted positively towards the monitoring:

> *I think most of the ladies have been quite positive regarding it, I think they like to see the carbon monoxide levels coming down.*

Interview, Community Midwife 6, Trust A, 27th February 2014

However, staff also recognised that CO monitoring sometimes put smokers in an awkward position with HCPs, leading to deceitful behaviours:

> *…people tell porkies [lies]. They tell porkies in front of us. 'How many do you smoke?' And they will say 'oh, just one or two a day', and then their reading is like twenty.*

Paired interview, RPT Midwife 7, Trust E, 21st July 2014

Summary

1. Universal CO monitoring appeared to create additional positive outcomes.
2. The intervention offered benefits to Trusts at every level, by introducing CO monitoring.
3. Enhanced ability to performance manage CO monitoring by staff.
4. Positive reactions from pregnant smokers towards CO monitoring.
5. CO monitoring could put pregnant smokers in a position where it was difficult to remain truthful.

Organisations differed in terms of:

1. Trust protocols for frequency of CO monitoring
2. Trust protocols for collecting CO monitoring data on non-smokers
3. Pre-trial establishment of universal routine CO monitoring in Trusts.

Effect of the setting on the hypothesised mechanism

Overall this procedure was accepted and seen positively by staff; they reported pregnant smokers viewed it favourably too. It offered several benefits to staff but also created tensions for continuing smokers. However, there was variation in implementation across settings rather than one standard. Variations in context introduced variability regarding the effect of the setting on this mechanism.

d. How does introducing changes to the language of the SS message, from midwives/MCAs/administration staff/SS advisors, increase quit rates?

The language used by staff with pregnant smokers was found to be key to a successful quit. For evidence from the data (active ingredient, barriers, facilitators) see mechanism 6.

e. How does increasing buy-in to the intervention by HCPs improve outcomes?

According to NPT, staff are more inclined to support the intervention if they have bought into the idea of it (May and Finch, 2009). There is then the expectation that they will work to embed it in normal work routines (May and Finch, 2009).

Active ingredient

A new discourse to promote motivation to quit within the therapeutic relationship and clinical encounter was recognised as a way to increase quit rates.

Facilitators	*Barriers*
Buy-in of HCPs An effective unthreatening way to confront smoking behaviour	Ill-equipped to deal with unease with challenging smoking behaviour

Increased buy-in of HCPs and change to the language

The intervention introduced a new discourse to promote motivation to quit within the therapeutic relationship and clinical encounter:

> *I think people didn't want to have those conversations and risk someone getting defensive and upset or anything like that ... So I think there has been a big shift in the way we've gone about talking to pregnant women about these things*.

Group interview, General Stop Smoking Advisor 10, Trust A, 31st January 2014

Some midwives were reported to be uneasy with confronting women about smoking more than other unhealthy behaviours:

> *It seems it appears to be harder for them [midwives] to approach that or to say no cigarettes at all, but they quite easily say not to drink*.

Interview, SSS Manager 7, SSS E, 17th July 2014

The intervention offered maternity staff a way to confront smoking behaviour in a caring, supportive manner:

> *Initially it is like anything new, and it is like domestic violence, asking those questions. Initially it is hard. You are prying, and it is a sensitive subject, but when you get used to using the right phrases, and [babyClear© lead trainer] talked about crib cards, and we made some sheets with suggestions for opening introductions and the words to use, and once you have said them so many times it is easier*.

Interview, Pregnancy Specialist SS Advisor 2, SSS C, 6th May 2014

It was noted that there was a fine line for HCPs to walk between being received as judging rather than caring:

> *...because when you're trying to, especially when you're first booking a lady, you have to build up that rapport, so you don't want to ruin that rapport straight away by giving a hard-hitting fact on smoking, in case she thinks that you're judging her and thinking 'I don't want to see her, she'll be rattling on about smoking again', so you know you have to be diplomatic about how much you do say at each appointment really*.

Interview, Community Midwife, team lead 4, Trust A, 4th February 2014

Administrative staff learnt to constructively challenge women's views:

> *Sometimes they'll say to us, I need that kick up the bum and I'll say look, I'm going to tell you something, but I don't mean to come across harsh. I'll always state that to them, so they don't think I'm being nasty 'cause I'm not saying it in a nasty way, I just want them to have an understanding of what could possibly happen*.

Interview, Administrator 4, SSS G, 6th August 2014

MCAs learnt to leave an open door if someone did not quit:

> *Yes. I would never ever not give anyone a negative message to see them, 'not done it this time, never going to see you again'. We will always leave with 'right, just keep thinking about it, there's our number, we're here Monday to Friday, and we can come and see you whenever is best for you'. And I sometimes think that if we leave it like that it is like an open door for them to think 'right'. We leave them with leaflets and things and even if they are passing the kitchen and they see that leaflet and sometimes they are going to think 'ah'…*

Interview, MCA 1, Trust A, 30th January 2014

The intervention's declared aim was to empower pregnant smokers. This included explaining the latest research and thereby offering the possibility of a more fully informed choice:

> *A better understanding about what's in a cigarette that you can actually discuss that with them. Make it clear, we should have known it but somehow we didn't, that the nicotine is the bit that's the addiction but what about everything else that's in there, we've probably been told in the past but just whooshed straight over your head, whereas this seemed to condense everything and make much more sense.*

Interview, Community Midwife, team lead 3, Trust A, 27th February 2014

It was recognised that the way HCPs were taught and what was generally expected of them in other clinical scenarios used styles which tended to be disempowering for patients;

however, this was understood to be ineffective when working with behaviour change associated with addiction:

> *What it is, it's about equipping, empowering women and motivating them, but equipping the staff with the skills to be able to take them through that behaviour change.*

Interview, Lead Trainer, 24th November 2014

Motivational interviewing was used with the intention of empowering women to make fully informed choices. Sometimes they really took note:

> *Sitting here and really telling them what they are doing to the baby, and you can see their faces change. It is hard because you are telling them things they never ever want to hear, but on the other hand you have to say 'but I can help you with that. That is what I am here for, I am here to help you. I am here to support you, I am here to give you the treatment that you need.'*

Interview, MCA 1, Trust A, 30th January 2014

Sometimes they took a while to be convinced, others just decided against, although most accepted the referral:

> *...we'll be happy to sit and talk and we understand the risks, it's just that they're not quite at that stage where they feel that they can quit but as I say, sometimes just by talking and seeing how they're getting on each visit, quite a few by the end start addressing the situation but then you get some that just, it's just lip service and yes, they'll listen to you but there's no way they're going to actually access it. They're happy for you to refer.*

Interview, Community Midwife 6, Trust A, 27th February 2014

Sometimes they went on to quit:

> *She said like in this phone call, she said I thought about what you said, and I just went straightaway to the service and asked for an appointment and quit. She said I didn't like it, I don't like it now. A lot of women don't like it; they do it because it's a habit; they don't even like the taste of it. A lot of people stop because morning sickness makes them stop, so the responses are different. Some of them are still dead certain that they don't want to, and I tell them a few possibilities of things that can happen and say to them I'll phone you in a fortnight, think about it. That gives them plenty of time and one of them had quit by that fortnight of getting back to them. She said I didn't want to because I didn't think I could, but when you told us it played on her mind to the point where she was like I can't really smoke anymore. She didn't even get the product; she just couldn't physically smoke anymore; it put her off and she quit. So, it's not telling*

them or forcing them to do something; it's helping them make their own choice and that's what I'm there to do.

Interview, Administrator 4, SSS G, 6th August 2014

Other times they did not:

...some of them, they'll just hang up on you.

Interview, Administrator 4, SSS G, 6th August 2014

Summary

1. The new discourse introduced with the intervention reached out to the pregnant smoker, to persuade, encourage and empower her to quit smoking.
2. Most women were persuaded not to opt out of the referral to SSPSs and some women were motivated and strengthened enough to act to quit whereas others were not.

Individual staff varied in terms of:

1. Level of buy-in to the new discourse
2. Ability to weave in scripted phrases and move towards an empowering conversation.

Effect of the setting on the hypothesised mechanisms

These mechanisms were largely successful. Most staff integrated the training into their own practice. Variation in individual buy-in and ability would be the main influence of the setting on the mechanism.

Key findings

Staff generally found the training beneficial, equipping them further to become effective SS practitioners. Nevertheless, many thought it repeated previous training needlessly and/or was inaccessible within work constraints. Inaccurate assumptions were made about local services by the training designers, which threatened feasibility and fidelity. These criticisms could be tracked back to the origins of the training package. It was designed by the provider, to include Trust senior management agendas, but without consultation with middle managers or frontline staff.

7.6.11 Mechanism 11 - Whole systems approach

How does changing the systems to accommodate the babyClear© package increase quit rates?

The evidence:

The interconnectedness of systems has been recognised increasingly, so for example, it has been noticed how implementing a change in one area of a complex system must take into consideration multiple contexts elsewhere in the system, before it can be fully implemented (Bonell *et al.*, 2012; Moore *et al.*, 2014). A whole systems approach has been recommended for implementation where complexity is concerned rather than a narrow focus on the immediate context only (Greenhalgh *et al.*, 2004; Iles and Cranfield, 2005; Moore *et al.*, 2014; Grant and Hood, 2017; Craig *et al.*, 2019).

a. How does providing sufficient resources to deliver the babyClear© package increase quit rates?

NICE PH Guidance (2010) points out the importance of adequate resourcing and the barriers created without it.

Active ingredient

Well-resourced contexts where NICE PH Guidance was already more embedded were perceived as more likely to increase quit rates.

Facilitators	*Barriers*
Greater compliance with NICE PH Guidance (2010) Pre-existing and ongoing/additional resources Greater integration between organisations	No clear baseline Absent resources Reducing budgets Restructuring of SSS Unequal implementation of the package

Implementation of NICE PH Guidance (2010) displayed considerable variation across the region. It challenged all services, but greater compliance had already been achieved in some areas compared with others.

> *…lack of consistent regional training, lack of access to things like carbon monoxide monitors which were a staple of what the NICE guidance said that all midwives should be using, simply was the fact that not everybody had access to them.*

Interview, Fresh Specialist 1, Fresh NE, 17th June 2014

The resources made available in terms of money, services and staff time varied:

> *We had to delay training of those midwives because we have had problems with staffing, with sickness, with actually covering the Unit and so*

we couldn't release them, initially to go to the initial [RPT] training sessions.

Interview, Senior Manager 9, Trust H, 24th November 2014

Effect of the setting on the hypothesised mechanism

Organisations differed in terms of pre-existing inputs which led to variance in the ability of the context to facilitate the implementation of the intervention.

b. How does increased communication/ integration between SSPS and maternity services increase quit rates?

NICE PH Guidance (2010) points out the importance of feedback on progress from the midwife to the quitting smoker to motivate and support her.

Feedback loops have been demonstrated to be vital in mechanisms 2, 3, 7 and 10c, where their importance in raising quit rates has been identified. This has been through a combination of monitoring and updating records so that staff are well-informed and can take the relevant action e.g. increase compliance with NICE PH Guidance (2010) standards, pursue contact with women appropriately, know a woman's level of engagement with SSPS prior to each appointment. These result in tightly structured support for the pregnant smoker.

Active ingredient

Systems and relationships between maternity and stop smoking in pregnancy services that supported feedback loops and a common understanding of how the package functioned were seen as supporting an increase in quit rates.

Positive, inter-organisational relationships between staff were also understood to encourage pregnant smokers to quit.

Facilitators	*Barriers*
Efficient data management systems Regular communication between maternity and stop smoking in pregnancy services Understanding of the roles and responsibilities of all staff along the pathway	Inefficient data management systems Irregular communication between maternity and stop smoking in pregnancy services Lack of understanding of the roles and responsibilities of all staff along the pathway

Effect of the setting on the hypothesised mechanism

It cannot be assumed that communication channels are present and/or open. Variations in context in relation to communication introduced variability regarding the effect of the setting on this mechanism.

Key findings

Pregnant women were seen in a variety of contexts, requiring a whole systems approach for optimal care. However, systems were not fully integrated and the ability of staff to treat women holistically was challenged. System changes were required to comply with this mechanism; however, the continuing diversity of SDMs and multiplicity of contexts, including variable resourcing and patent communication channels, meant that often mechanisms were not able to operate as intended.

7.7 Conclusion

Key findings

The intervention is likely to have been effective in improving smoking cessation rates among pregnant women in the NE of England; an assertion supported by the effectiveness evaluation (Bell et al., 2018) and the subsequent reduction in SATOD figures across the region (PHE, 2019). However contextual variables impeded progress; the reduction in smoking rates and adverse health outcomes for mothers and babies are likely not to have reached their potential and sustainability has been questioned.

NPT used with a logic model has allowed me to

- clarify the feasibility of the intervention, and how amenable it was, to being implemented with fidelity
- explain the underlying contexts at micro/meso levels and how they have assisted or hindered implementation.

In Chapter 7 I have moved the thesis towards answering RQ 1 in two ways. Firstly, I have identified the contexts of implementation. Secondly, I have identified and elaborated the active ingredients, barriers and facilitators, from data that were collected using NPT as a basis for the question schedule.

In conclusion, it was known that neither the inherent logic model that was assumed by the intervention designers, nor the mechanisms of impact, were made explicit before the start of the implementation, as the process of development of the intervention was pragmatic rather than experimentally based. I have made explicit the types of implementation factors that

were overlooked in trials evidence. I have then moved on towards answering RQ 2, by taking the descriptions of contexts and the logic model and examining them for the intervention's potential for normalisation and identified elements of the theory-practice gap. The analysis shows that the intervention was designed with a standard context in mind, but that contexts varied widely, and the intervention struggled to be sufficiently flexible to accommodate the variance. No causative conclusions can be drawn, using this study design, regarding the effectiveness and cost-effectiveness of the intervention itself.

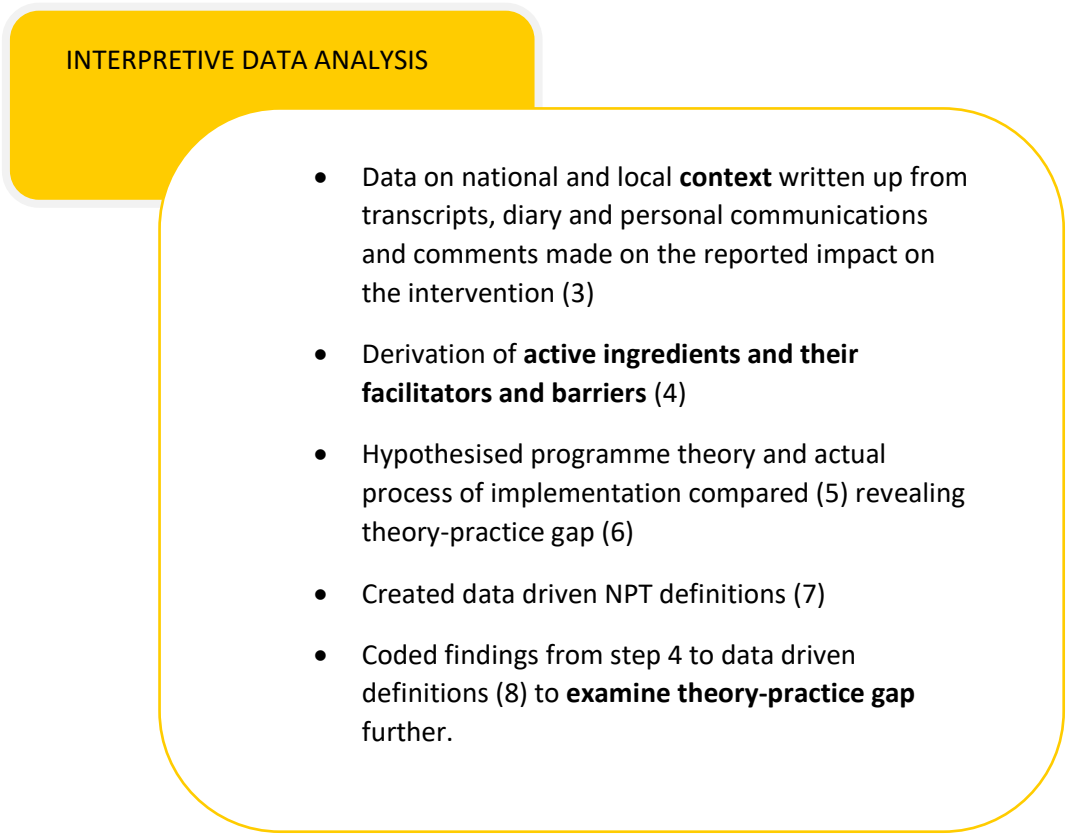
I will now consider these findings in Chapter 8, through the lens of NPT, to determine the usefulness of this theory in identifying the implementation process and by determining what is necessary for feasibility, fidelity, normalisation and sustainability, thus answering the three research questions.

Chapter 8 ANALYSIS and FINDINGS 2

8.1 Introduction

In this chapter I use NPT to develop the analysis and primarily focus on answering RQs 2 and 3, as summarised in Figure 8-1, focusing on the last box in the steps of analysis.

Figure 8-1: Steps in analysis – interpretive data analysis (same as Figure 7-1)



Chapter 7 described and reported on context, mechanisms of impact, active ingredients, barriers and facilitators of the example intervention and its implementation by comparing the hypothesised mechanisms with those in the data (Steps 3 – 6). Overall, in this chapter, I will now explore and critique **how NPT can be used** to bring to light the factors that affect intervention outcomes, but which are neglected in trial methodology, and comment on the findings (Steps 7 & 8).

Chapter 8 is divided into two parts. Firstly, in 8.2–8.5, I focus on continuing to answer RQ 1. I will show how, by combining the logic model and the NPT framework (defined by study data - Appendix 11.5.4), it is possible to examine the process of implementation using the lens of NPT. My focus in the second part of this chapter (8.6-8.7) is on addressing RQs 2 and 3. I

examine the theory's usefulness in considering the features raised by the RQs, and its ability to inform the implementation of complex interventions with fidelity, whilst allowing for some adaptation. I will reveal how applying NPT can be useful in identifying the implementation process more precisely.

In summary, in this chapter I will:

- *Create definitions of core and sub-constructs of NPT from the data (see 8.2)*
- *Apply the lens of NPT to active ingredients, barriers and facilitators by coding them to data-driven NPT concepts (see 8.3-8.5)*
- *Relate findings to the theory-practice gap (see 8.6-8.7)*

8.2 NPT framework definitions

The first stage in applying the NPT lens to the data was to create construct definitions, also called coding guidelines (MacFarlane and O'Reilly-de Brún, 2012; Atkins *et al.*, 2017; Segrott *et al.*, 2017). The terminology of NPT is necessarily broad, so that it can be applied widely; however, this can make the definitions feel turgid to use and distant from the data. To answer RQ1, I worked up definitions of NPT sub-constructs then core concepts from the data. This was achieved by using definitions given in May & Finch (2009) and supplemented by other definitions written by authors' who have used NPT in similar settings (see Appendix 11.5.3). I summarised the data in each NVivo node, then coded the summaries to each sub-construct in a preliminary analysis (Appendix 11.5.4), then created data-driven coding guidelines (see Tables 8-1 to 8-4). I have also tabulated how the guideline might inform a process evaluation (see column 3).

Table 8-1: Data-driven coding guidelines of NPT concepts

Core concept and sub-constructs	Coding guideline derived from babyClear© evaluation data	Ability to inform process evaluation
COHERENCE	Working out how and if babyClear© makes sense to the implementers in terms of its aims, any increased benefits and its workability in context	
Coherence – differentiation	Identifying how babyClear© differs from previous practice, if at all	Ability to identify how babyClear© is different from previous practice and how it is not
Coherence – communal specification	Sharing, or lack of it, about what babyClear© aimed to do, how it expected to do it and what were the practical implications	Helped to identify how babyClear© aims and expectations could be shared but also the contradictions and practical blocks to sharing
Coherence – individual specification	Clear communication, or lack of it, leading to individual staff understanding their responsibilities and tasks	Assisted in revealing the helps and hindrances to clear communication of responsibilities and tasks
Coherence - internalisation	Framing information about babyClear© to demonstrate its value in context	Elicited the mechanisms by which babyClear© was internalised and related them to the specific context

Table 8-2: Data-driven coding guidelines of NPT concepts CONTD. 1

Core concept and sub-constructs	Coding guideline derived from babyClear© evaluation data	Ability to inform process evaluation
COGNITIVE PARTICIPATION	Demonstration of the level of buy-in from stakeholders, characterised by the conversion of planning and talking into preliminary equipping	
Cognitive participation - enrolment	Drawing up a plan that is led confidently, is consistent, feels right and is workable in context, or not.	Identifies the requirement for consistency, feel and workability and draws out the challenges to them
Cognitive participation - activation	Integrating, or not, shared tasks between maternity and SS services	Identifies helps and challenges to organising shared tasks
Cognitive participation - initiation	The degree to which key individuals equip and enthuse others and drive babyClear© forward	Demonstrates the mechanism by which babyClear© is driven forward or restrained
Cognitive participation - legitimation	The degree to which babyClear© is supported in principle and equipped in practice by the context into which it is being implemented	Ability to confirm the importance and centrality of babyClear© to the implementing organisations

Table 8-3: Data-driven coding guidelines of NPT concepts CONTD. 2

Core concept and sub-constructs	Coding guideline derived from babyClear© evaluation data	Ability to inform process evaluation
COLLECTIVE ACTION	Bringing together all the implementers at organisational, system and individual levels to put the babyClear© package into practice in each location and setting	
Collective action – skill set workability	Re-allocating tasks, introducing and training in new tasks, measuring performance and the effect of variation on organisational contexts	Identifies the detail of logistical challenges and the differential effects of context
Collective action – contextual integration	The degree to which the organisation and system contexts do/ do not support the implementation of babyClear©	Underlines the paramount importance of overarching contexts which are beyond the power of individuals to control
Collective action – interactional workability	The degree to which carrying out babyClear© is easy to integrate into the work of implementing organisations	Ability to identify the features which enable/hinder the work of HCPs
Collective action – relational integration	The degree to which individuals and system contexts do/ do not support the implementation of babyClear©	Ability to identify the factors that enable/hinder staff confidence in the babyClear© package at the individual and team/local system level

Table 8-4: Data-driven coding guidelines of NPT concepts CONTD. 3

Core concept and sub-constructs	**Coding guideline derived from babyClear© evaluation data**	**Ability to inform process evaluation**
REFLEXIVE MONITORING	Measuring the degree of success in adapting to change at all levels	
Reflexive monitoring - reconfiguration	The degree to which practices require adapting to accommodate babyClear©	Identifies the adaptations required for full implementation
Reflexive monitoring – communal appraisal	The processes for shared data collection and communication of review and evaluation findings	Points out local variation in sharing of reviews and evaluation of progress and how it affects the processes that exist and their quality
Reflexive monitoring – individual appraisal	The way individuals judge their own contribution and that of the systems they work in on the implementation and sustainability of babyClear©	Opportunity for personal staff perspectives to be considered
Reflexive monitoring - systematisation	The degree to which babyClear© related changes are identified, measured and found to be sustainable	Useful to identify the unmeasured changes, effect of local variation and threats to future sustainability

Next, I have used the original logic model (see 6.3) and applied the NPT-concept, data-driven coding guidelines to the findings set out in Chapters 6 & 7 on context, active ingredients, barriers and facilitators of the mechanisms of impact, required for the process of implementing the intervention (Appendix 11.5.2). These further findings are below and encapsulate both what NPT was able to identify and, also, areas that the data suggest are significant but are missed by the theory. Some active or core ingredients, that were additional to those already noted, were also identified at this stage.

8.3 Inputs

Findings

NPT concepts have relevance for viewing systems and structures at regional, organisational, team and individual levels e.g. in relation to compliance with NICE PH Guidance (2010). However, this can be confusing during analysis, as the different levels are not differentiated within the concepts or theory.

NPT does not grapple comprehensively with the pre-existing context; however, it does draw out the variations between organisations and other facilitators and barriers to normalisation during implementation.

Summary: A thorough understanding of the pre-existing context is a vital foundation for the implementation. Without it, the process faltered. In future, this could be remedied by combining NPT with logic modelling, during pre-implementation.

8.4 Outputs, Activities

Findings

NPT reveals facilitators/threats to normalisation both at the organisational and team level.

NPT helps to understand the progress of implementation through the process and where and why it gets ‘stuck’.

Pre-existing contexts varied and affected the implementation, but NPT does not consider the initial context, except peripherally e.g. in coherence/differentiation.

Implementation weaves between organisational and individual factors; it is unclear how to systematically apply NPT. This raises the questions: At what contextual level is it relevant to apply it? How do the levels and factors interrelate in NPT?

NPT does not embrace the broad environment or specific context of the target population e.g. smokers’ readiness to quit, only considering factors associated with effectiveness, such as the outcome e.g. quit rates. Again, this raises questions, i.e. should the effect of the environment and context on the target population be considered, and if so, how?

Summary: Normalisation was halted due to contextual factors that either had not been considered or were not anticipated at the outset.

8.5 Outputs, Procedures

8.5.1 Universal carbon monoxide monitoring

Findings

A secure foundation for Coherence, Cognitive Participation and Collective Action, was reliant on active, senior support to ensure training and systems were in place.

The intervention was based on evidence understood to be coherent, but three implementation factors limited Coherence:

- The pathway was not always applied as directed in the guidance
- SS training was non-statutory, so other healthcare workers did not receive it
- Governance rulings across organisations differed.

Feedback loops were important for consistent and meaningful monitoring and, where they existed, good practice was reinforced. Many areas struggled to complete them; so here Coherence and Cognitive Participation faltered, suggesting that the foundation for Collective Action would be weakened.

Aspects of CO monitoring, which are central to the intervention, touched on all four concepts.

Belief and practice go hand in hand; they need one another.

Belief affected how well the practice of CO monitoring was implemented.

Active ingredients

- Active, senior support to ensure training and systems were in place
- Feedback loops to ensure consistent, meaningful monitoring and reinforcement of good practice
- New CO analysers, reduced threshold
- Belief and buy-in to the practice.

8.5.2 Opt-out referral

Findings

Belief in the activity and compliance with systems was important; a flexible response assisted the process but those slow to accept change hindered it.

Training in new activities often included elements of all four concepts Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring and all sub-constructs of a concept.

This was especially so for Collective Action. This resulted in distinction between concepts being lost.
The activities designed to integrate services were operational, but only in some areas, recognising how systems interfered with compliance and normalisation was threatened.

Active ingredients

- Belief in and feasibility of the activity
- Flexibility in response to change
- Activities designed to integrate services.

8.5.3 Increased speed of referral

Findings

NPT identified how systems allowed/impeded implementation of best evidence.
It revealed how variation within systems, as well as individuals' perceptions, compromised fidelity; hence NPT was working at both levels.

Active ingredient

- Systems that promoted efficiency in terms of administration of referrals, appointments, communication and feedback.

8.5.4 Motivational interviewing

Findings

NPT made it very clear that without access to the training the process of normalisation was halted.
There were mixed findings around differentiation; it was helpful to be clear when something was clearly new, but also, if the intervention accepted and used activities of usual care, such as motivational interviewing, there was no debate over its acceptability. The issue of differentiation became over how the new practice was used or if it was appropriate to develop its use.

Active ingredients

- Access to the training.

8.5.5 Quitting completely

Findings

NPT clearly identifies how a pre-action, thinking stage is fundamental for staff. If there is a problem with Coherence, then the implementation cannot advance securely; it will be held back in specific areas.

It is not as easy to recognise later thinking stages or report on them, as they are iterative and non-linear.

NPT concentrates on the service that is providing the intervention, rather than the effectiveness outcomes of the intervention itself. NPT is not designed to understand if the complex intervention is internally effective.

Active ingredients

- A pre-action, thinking stage is fundamental for staff to fully engage with the intervention.

8.5.6 Speed of contact/timeframes

Findings

Existing organisational philosophy or ethos, part of the environment that is critical to normalisation, is not really incorporated into the theory; only on the edge of one concept, Coherence.

Similarly, the wider environment that organisations are operating in is not considered e.g. political, financial and social.

Facilitators of the target population for the intervention are not within the scope of NPT when focusing on staff; however overall effectiveness will be down to a combination of factors from both aspects.

Active ingredients

- A philosophy that supported prioritisation of the SS message.

8.5.7 Increased contact

Findings

NPT clearly identified how increased contact between pregnant smokers and SSPS was well differentiated from usual care.

NPT also consistently identified: the facilitators and hindrances to organising these shared tasks related to increasing contact, the importance of legitimating the changes and the challenges associated with activating them.

Barriers to active ingredients that would ensure increased contact were primarily noticed at the point of taking action; however, it is evident that the precursors to them were laid with insecure Coherence and Cognitive Participation.

Active ingredients

- Smooth organisation of shared tasks, within and between organisations
- Senior staff and champions who legitimate the changes by explaining and reinforcing why they are important and different, recruit people to the cause and keep them on-board and smooth the day to day issues and actions that make it happen.

8.5.8 Risk Perception Tool

Findings

Belief in something has carry over into planning and preliminary equipping; without belief in it, it is unlikely to be thoroughly implemented and normalised.

A code relating to organisational culture: "Organisations that embraced change; flexible and adaptable" – did not fit into any NPT concept; it has most relationship to Coherence but even here it was far from clear how it would fit.

Lack of Coherence/internalisation was apparent amongst staff when it was needed to overcome resistance to introducing the RPT.

Lack of Collective Participation around the RPT - where you would expect to see it if it was to be normalised - was identified.

8.5.9 Follow up options

All areas offered a variety of options; some more, others less. Different areas offered different varieties (see 7.4). It was not possible to identify with certainty the active ingredients in different models of follow up from the staff data.

8.5.10 Summary

To answer RQ 1 - to elaborate and identify the process of normalisation – I have sifted the contexts, active ingredients, facilitators and barriers of each procedure within the logic model using the NPT data-driven definitions. By using NPT, I identified that the key requirement to drive the implementation forward is **active senior support within organisations, expressed in effective leadership.** Often this is partly achieved through appointing a champion. This high management level of support is required to:

- Ensure access to training for all providers of SS advice to pregnant smokers
- Promote staff belief and buy-in to the implementation process

- Facilitate fidelity and feasibility e.g. through system change
- Promote and enable joint-working between organisations
- Prioritise the work associated with the implementation
- Legitimate working towards normalising the intervention.

I will now draw together the results of this analysis to explore the utility of NPT when implementing this complex intervention.

8.6 Utility of NPT – NPT as an organising framework

The following findings, on the utility of NPT as an organising framework, are looking at answering RQ 1 i.e. how successfully it allowed identification and elaboration of the process of normalisation of a complex intervention. As NPT was applied, I reflected on its strengths and limitations for this purpose; I noted its relevance and ease of use; these thoughts are now presented. First, I shall tabulate the limitations (Tables 8-5, 8-6), then the strengths (Table 8-7, 8-8), when using NPT to examine the data. Finally, I will tabulate areas where strengths and limitations are mixed (see Table 8-9).

8.6.1 Limitations of NPT for data organisation

Table 8-5: NPT as an organising framework (1) – data organisation/ limitations

LIMITATIONS	
OVERLAP	
Finding	**Comment**
Overlaps in concepts	Makes them difficult to apply, especially sub-constructs. How necessary (or manageable) is it to use the sub-constructs?
Similarity between sub-constructs i.e. where elements of the factor fall into all four within a core concept.	Is it easier to use 4 broad concepts only and sub-constructs as illustrations of what each concept covers?
Training in new activities often included elements of all four concepts Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring and all sub-constructs of a concept.	Difficult to apply, especially Collective Action. Resulting in distinction between concepts being lost.
Aspects of some intervention procedures, e.g. universal CO monitoring, touched on all four concepts.	Concepts not sufficiently specific (thinking of literature searches) or alternatively what does this tell us? How should we handle this information?
LINEARITY	
Finding	**Comment**
Becomes less linear, more concepts in play at one time as implementation proceeds.	Difficult to think of as other than linear; how could NPT be presented/reported or made more non-linear while retaining its strengths?
Clearly proceed into Collective Action i.e. linear but shows how Coherence and Cognitive Participation remain a part of making progress i.e. cyclical element within and between concepts.	Not discrete steps but overlapping, back and forth, but some must come before others, with overall forward direction of travel.

Table 8-6: NPT as an organising framework (1) – data organisation/ limitations (CONTD.)

LIMITATIONS	
MISFITS	
Finding	**Comment**
Variable application of the package across areas, not within one organisation.	How to apply core concepts across organisations rather than within them?
How to report to reflect good practice as well as less good?	
Facilitators of the target population for the intervention are not within the scope of NPT when focusing on staff.	Overall effectiveness will be down to a combination of factors from both staff and patients' aspects; two separate analyses would be necessary to incorporate multiple populations including patients.
NPT was unable to codify "Organisations that embraced change; flexible and adaptable".	This code has most relationship to Coherence but even here it was far from clear how it would fit – this is perhaps more contextual and ephemeral. About the nature/ethos/culture of an organisation.
THEMES EXCLUDED BY THE CONCEPTS	
Finding	**Comment**
Elements that were not in the logic model but were part of the necessary context i.e. facilitators; such as staff to champion it, a conducive organisational culture, were diffused across the analysis.	This made it difficult to draw these required elements of context into a cohesive theme.
Resources not given enough significance in NPT i.e. they are 'deal-breakers'.	Resources were initially coded mostly under: Collective Action (contextual integration), a little under Cognitive Participation (activation) – but a) not clear as an issue in NPT definitions worked up from the data and b) the sub-constructs do not really grasp the nettle where resources are concerned e.g. do not clearly identify resources as an issue, explore the complexity of management decisions, supply chains etc.
Importance of feedback loops, not specific within NPT, but are revealed by the data (like resources).	Important for consistent and meaningful monitoring, where they reinforced good practice. Many areas struggled to complete them; so here Coherence and Cognitive Participation faltered, suggesting that the foundation for action would be weakened.

8.6.2 Strengths of NPT for data organisation

Table 8-7: NPT as an organising framework (2) – data organisation/strengths

STRENGTHS	
LINEARITY	
Finding	**Comment**
NPT made it very clear that without access to the training the process of normalisation was halted.	Another 'deal-breaker' that was recognised but it was unclear how to report it with this level of significance. This raises the question: are all 4 concepts equally important?
Showed that belief and practice go hand in hand; they need one another.	
Belief affected how well the practice of CO monitoring was implemented.	
Belief in something has carry over into planning and preliminary equipping; without belief in it, it is unlikely to be thoroughly implemented and normalised	
Barriers to active ingredients that would ensure increased contact between staff and pregnant women were primarily noticed at the point of taking action.	The precursors to the barriers were laid with insecure Coherence and Cognitive Participation.
A secure foundation for action, Coherence and Cognitive Participation, was reliant on active, senior support to ensure training and systems were in place.	Additional to logic model; identification of requirements for normalisation.
Helps to understand the progress of implementation through the process and where and why it is slowed or halted.	
Belief in the activity and compliance with systems were important; a flexible response assisted the process but those slow to accept change hindered it.	

Table 8-8: NPT as an organising framework (2) – data organisation/strengths (CONTD.)

STRENGTHS	
MISFITS	
Finding	**Comment**
The intervention was based on evidence understood to be coherent, but three implementation factors limited Coherence: I. The pathway was not always applied as directed in the guidance II. SS training was non-statutory, so other healthcare workers did not receive it III. Governance rulings across organisations differed.	Factors additional to the logic model, required for normalisation, identified using NPT.
Feedback loops were important to consistent and meaningful monitoring where they reinforced good practice. Many areas struggled to complete them; so here coherence and cognitive participation faltered, suggesting that the foundation for action would be weakened	Factors additional to the logic model, required for normalisation, identified using NPT.
COMPLEXITY	
Finding	**Comment**
The number of concepts/sub-constructs that a facilitator or barrier comprises may reflect the complexity of introducing it and making it operational.	
Confirms logic model as far as it goes. Basic assumptions stated in the logic model require more detail but broadly they are supported by the findings.	See mechanism summary points in 7.6 e.g. for universal CO monitoring 1 – 3ppm as per logic model and evidence base. Summary point 1 for increased speed of referral as per logic model and evidence base.

8.6.3 Mixed findings on NPT for data organisation

Table 8-9: NPT as an organising framework (3) – data organisation/mixed strengths and limitations

MIXED STRENGTHS and LIMITATIONS	
OVERLAP	
Finding	**Comment**
When there is significant overlap between concepts it is confusing to code and analyse using NPT.	NPT does assist in drilling down into the separate elements, revealing the nuances.
Use of Coherence/differentiation - other findings revealed outside of NPT e.g. new discourse, champion etc.	Does this sub-construct attract all the things that fall outside all other categories within the framework?
LINEARITY	
Finding	**Comment**
NPT clearly identifies how a pre-action, thinking stage is fundamental. If there is a problem with Coherence then the implementation cannot advance securely, it will be held back in specific areas.	It is not as easy to recognise later thinking stages or report on them, as they are iterative and non-linear.
BOUNDARIES/COMPLEMENTARITY	
Finding	**Comment**
NPT concentrates on the service that is providing the intervention, rather than the effectiveness outcomes of the intervention itself.	NPT is not designed to understand if the complex intervention is externally effective; this is where other methodologies are useful.
SPECIFIC CONCEPTS	
Finding	**Comment**
There were mixed findings around Coherence/differentiation.	This sub-construct was helpful in clarifying when something was new, but also when the intervention accepted and used activities of usual care, such as motivational interviewing, for which there was no debate over its acceptability. The issue of differentiation became over how it was used or if it was appropriate to develop its use.
The sub-construct Reflexive Monitoring/reconfiguration is used far more than any other in this concept.	This sub-construct almost seems to fit elsewhere, in a category of its own. Is it just that long term evaluation is rarer?

8.7 Utility of NPT - NPT as an interpretive framework

This next section considers RQs 2&3 and begins to interpret the data. For this purpose, I derived ten headings from the research questions, the literature and the analysis reported above. They are as follows:

- Exploring context
- Identifying delivery mechanisms
- Identifying mechanisms of impact
- Identifying active ingredients
- Informing feasibility
- Informing sustainability
- Informing transferability
- Examining fidelity
- Exploring knowledge translation
- Exploring the theory-practice gap

8.7.1 Exploring context

Context is not specifically incorporated into any NPT concept but is an overarching influence on the implementation (May *et al.*, 2007b; Moore *et al.*, 2014; Craig *et al.*, 2019). The interview questions did not focus on context as they were based on NPT, but it was often referenced by participants at the micro, and to some extent, the meso level. Most contextual data collected at the macro and meso level was through personal communications and recorded in the field diary. See Tables 8-10 and 8-11 for the strengths and limitations relating to NPT when considering context.

Table 8-10: NPT as an interpretive framework (1) – context/limitations

LIMITATIONS	
CONTEXT	
Finding	**Comments**
Existing organisational philosophy or ethos, part of the environment that is critical to normalisation, is not really incorporated in the concepts; only on the edge of Coherence.	
Context has many levels of application: national/regional, organisational/system and team/individual or macro, meso, micro.	Confusing during analysis as the different levels are not differentiated within the concepts or theory.
NPT does not grapple comprehensively with the pre-existing contexts and how their variation affected implementation; yet organisational context is pivotal in most, if not all, steps in implementation; therefore, where there is variance this is a fundamental issue and affects the process and outcomes.	Excluded except peripherally e.g. in Coherence/differentiation.
The wider environment that organisations are operating in is not considered e.g. political, financial and social.	Makes it difficult to know how to handle (though not necessarily a criticism of NPT only).
Exclusion of organisational context/environment e.g. political, financial, that includes reducing budgets, frequent restructuring, uncertainty, pressure to perform to specific measures.	Makes it difficult to know how to handle (though not necessarily a criticism of NPT only).
Implementation weaves between effects from organisational and individual environmental factors, it is unclear how to systematically apply NPT to them.	At what contextual level is it relevant to apply it? How do the levels and factors interrelate in NPT? Makes it difficult to know how to handle (though not necessarily a criticism of NPT only).
NPT does not embrace the context/environment of the target population – is this a consideration or not?	e.g. smokers' readiness to quit, only considering factors associated with effectiveness, such as the outcome e.g. quit rates.

Table 8-11: NPT as an interpretive framework (2) – context/strengths

STRENGTHS	
SYSTEMS THINKING	
Finding	**Comments**
NPT concepts have relevance for viewing systems and structures at regional, organisational, team and individual levels.	e.g. in relation to compliance with NICE PH Guidance (2010).

8.7.2 Identifying mechanisms of delivery and impact

The hypothesised mechanisms were identified from NICE PH Guidance (2010) and associated literature (see 6.4). Data derived from an NPT-based collection tool (see 5.3.2), when coded to NVivo nodes for each procedure in the logic model, provided the information on the actual mechanisms (see 7.6). The hypothesised and actual mechanisms were then ready to compare, which allowed the active ingredients to be identified (see 8.5). For the utility of NPT in identifying mechanisms see Tables 8-12 and 8-13.

8.7.3 Identifying active ingredients, barriers and facilitators

Through thematically analysing the data coded to NVivo nodes for the inputs and outputs of the logic model the active ingredients readily became clear. They were identified from studying the facilitators and, conversely, the effect where they were absent. The only limitations found in using the theory to identify active ingredients were those associated with context (see Table 8-10). For the utility of NPT in identifying active ingredients, barriers and facilitators see Tables 8-12 and 8-13.

Table 8-12: NPT as an interpretive framework (3) - mechanisms/strengths

STRENGTHS	
IDENTIFYING FACILITATORS	
Finding	**Comments**
Draws out the variations between organisations and other facilitators to normalisation during implementation.	Makes this point strongly.
NPT clearly identifies how increased contact between pregnant smokers and SSS was well differentiated from usual care.	
Reveals facilitators to normalisation both at the organisational and team level.	e.g. Organisational and individual variation in provision and buy-in.
Reveals facilitators to normalisation in the activities designed to integrate services for opt-out referral that were operational in some areas.	Belief in opt-out; flexibility/adaptability/capacity in response to change Understanding the need for good documentation Types of SDM and integration of intervention.
NPT identifies how systems allowed implementation of best evidence.	
NPT consistently identifies: the facilitators to organising shared tasks related to increasing contact, the importance of legitimating the changes and the challenges associated with activating them.	

Table 8-13: NPT as an interpretive framework (3) - mechanisms/strengths (CONTD.)

STRENGTHS	
IDENTIFYING BARRIERS/THREATS	
Finding	**Comment**
NPT reveals how variation within systems, as well as individuals' perceptions, compromised fidelity.	e.g. of NPT working at both levels.
Exposes the gaps between theory and practice as reflected in lack of staff belief and buy-in to babyClear©.	e.g. in coherence but especially in cognitive participation.
Reveals threats to normalisation of RPT.	Identified lack of Coherence/internalisation when it was needed to overcome resistance to introducing the RPT.
Reveals threats to normalisation of RPT.	Identified lack of Cognitive Participation around the RPT where you would expect to see it if it was to be normalised.
Reveals threats to normalisation of intervention as a whole.	e.g. - Variable application of protocols - Lack of back-up from senior management to establish systems - Lack of buy-in from frontline staff
Reveals threats to normalisation of CO monitoring.	e.g. - Acceptance of new analysers - Clarity of new threshold - Organisational and individual variation in provision and buy-in
Reveal threats to normalisation of increased speed of referral.	- Summary points for mechanisms 2 & 3 increased speed of referral - Variance in organisations led to different ways of meeting this change - So long as active ingredients are adhered to adaptability may be acceptable.
Reveals threats to normalisation of opt-out referral system. The activities designed to integrate services for opt-out referral were operational, but only in some areas. Recognising how systems interfered with compliance and normalisation.	- Belief in opt-out; flexibility/adaptability/capacity in response to change - Understanding the need for good documentation - SDMs and integration varied.
Reveals threats to normalisation both at the organisational and team level.	
NPT identifies how systems disallowed implementation of best evidence.	
NPT consistently identifies: the hindrances to organising the shared tasks related to increasing contact, the importance of legitimating the changes and the challenges associated with activating them.	

8.7.4 Informing feasibility

The findings were examined for reports of feasibility and a clear pattern emerged, showing that NPT was able to identify the major contributors to successful implementation (see Table 8-14).

Table 8-14: NPT as an interpretive framework (4) – feasibility/strengths

STRENGTHS	
FEASIBILITY	
Finding	**Comment**
Identifying characteristics of systems that facilitated the intervention e.g. flexible	The converse identified the barriers e.g. inflexible
Identifying thought processes that facilitated the intervention e.g. belief in its coherence	The converse identified the barriers e.g. disbelief in its coherence
Identifying resources that facilitated the intervention e.g. efficient electronic data management software	The converse identified the barriers e.g. inefficient electronic data management software
Identifying contexts that facilitated the intervention e.g. senior support for SS	The converse identified the barriers e.g. lack of senior support for SS

8.7.5 Informing sustainability

The data on sustainability was limited, as NPT is concerned with the process of embedding through to normalising an intervention, with the intention that this will promote sustainability (May, Johnson and Finch, 2016). Delays during implementation also reduced the amount of data collected at these later stages of the process. Nevertheless, NPT was able to detect some likely contributors to successfully sustaining the intervention (see Table 8-15).

Table 8-15: NPT as an interpretive framework (5) – sustainability/strengths

STRENGTHS	
SUSTAINABILITY	
Finding	**Comment**
Identifying factors that were likely to lead to sustainability	i.e. the presence of an essential ingredient e.g. senior support, engagement, resources, prioritisation, feedback, integration between services or a flexible response to change or systems that accepted the intervention.
Identifying factors that were unlikely to lead to sustainability	i.e. a lack of an essential ingredient e.g. senior support, engagement, resources, prioritisation, feedback, integration between services or an inflexible response to change or systems that were inimical to the intervention.

8.7.6 Informing transferability

The identification of mechanisms of impact, active ingredients and their barriers and facilitators is a major step towards informing transferability, as meso/micro level contexts, which provide the environment that facilitate the mechanisms, are more likely to be successful. However, the broader macro/meso context was less clear but likely also to have a profound effect. The findings on informing transferability using NPT are summarised in Table 8-16.

Table 8-16: NPT as an interpretive framework (6) - transferability/ limitations and strengths

LIMITATIONS	
TRANSFERABILITY	
Finding	**Comment**
Unable to identify aspects of broader context required for normalisation	
STRENGTHS	
Finding	**Comment**
Identifying factors that were likely to lead to transferability	The presence of facilitators e.g. access to training, adequate resources, prioritisation, senior support etc.
Identifying factors that were unlikely to lead to transferability	The lack of facilitators/presence of barriers e.g. inimical systems, lack of resources etc.

8.7.7 Examining fidelity

NPT has clarified what the work involves in terms of resources, activities and procedures. It has identified the characteristics of organisations and systems that are necessary to implement with fidelity. Context, combined with active ingredients, was found to influence the fidelity with which an activity might be successfully implemented. Contexts were found to vary widely, so prospects for normalisation also varied. This ran counter to the design of the intervention and expectations for effectiveness. However, the importance of exploring the programme theory, mechanisms and active ingredients became apparent. It suggests that clarifying the core ingredients would allow practitioners to implement them with fidelity, while adapting other factors to suit the context. What NPT offers when it comes to other aspects of context, especially at the macro level e.g. the effect of government decisions, media campaigns and changes to commissioning structures, and meso level e.g. importance of an effective champion, is less clear.

8.7.8 Exploring knowledge translation

The intervention has taken the knowledge from trials, incorporated in NICE PH Guidance (2010), and tried to convert it into practice more effectively than previously. NPT found that

there were many hurdles, as the standard package was unable to flex around the variety of contexts; however, NPT was able to illuminate some of the reasons and identify the actual mechanisms and active ingredients. In this way the knowledge locked up in the trials-based evidence may be made more accessible; resulting in potentially more successful translation and implementation. Further work, incorporating data collected from pregnant women, would be necessary to explore any epistemological and ontological contradictions within the intervention (see 4.2).

8.7.9 Exploring the theory-practice gap

Initially NPT has enabled a comparison between the hypothesised and actual mechanisms which highlights the theory-practice gap and opens the door to understand what is needed for a complex intervention to become integrated into routine work practice. Making explicit the mechanisms and active ingredients offers some of the answers to scaling it up or transferring it successfully. This supports the argument that qualitative methods are most appropriate in these circumstances and that NPT can reveal "the work" that is required to successfully embed a change (May and Finch, 2009; Finch *et al.*, 2012). However, the findings also show that making explicit the necessary context has been a limitation when using NPT.

8.7.10 Conclusion

This section, 8.7, has contributed to answering research questions 2 and 3: To what extent does the NPT framework assist in understanding: feasibility, fidelity, sustainability and transferability?

NPT was a helpful way to envisage the process of implementation through to normalisation. Generally, it worked well when applying NPT concepts to organising the data to find the active ingredients, facilitators and barriers of each procedure within the implementation. Using the NPT data-driven definitions revealed both strengths and limitations of the theory. Some characteristics could be both a strength and limitation. NPT allowed identification of mechanisms, active ingredients, feasibility, sustainability, transferability, fidelity and exploring of knowledge translation and the theory-practice gap, however it struggled to address the multiple levels of context and environment.

Key finding

Context complexity, according to staff data, hindered many of the active ingredients and mechanisms. The key drivers - active senior support and leadership - were available in some organisations, to create a whole systems approach for effective and sustainable implementation. Similarly, key active ingredients and mechanisms were available to varying

degrees. These operated primarily as cognitive or physical drivers. Physical drivers included access to training, high flexibility/adaptability/capacity of systems in response to change, efficient data management systems with feedback loops, adequate resources and integration between services. Whereas cognitive drivers included prioritisation, legitimation, staff engagement, belief in opt-out and understanding of the need for good documentation. Sometimes both physical and cognitive drivers were present. The degree of support from the SDM in use, affected the ability of staff to implement babyClear© with fidelity and had implications for sustainability and transferability.

8.8 Conclusion of Chapters 7 and 8

The findings I have laid out in the last two chapters, are the result of a long, funnelling and sifting process from which I will answer the research questions. The discussion that follows in Chapter 9 represents my final "refining" to answer RQs 1, 2 & 3. In Chapter 7, I described the national and local context. This was a time of uncertainty, financial restraint and significant system change, forming a backdrop to the driving forward of a specific public health agenda. Each setting within the regional study area was unique. Mechanisms of impact, active ingredients and the barriers and facilitators to fidelity were readily identified from literary evidence and primary data. In Chapter 8, the NPT concepts 'coherence' and 'cognitive participation' enabled me to understand why an intervention may, or may not, reach a point of being feasible to implement. They allowed me to explore actors' thinking around what was planned, the behaviour that resulted and the degree to which a 'workaround' would be acceptable without compromising fidelity. I used NPT to illumine the reasons why trial-based activities and procedures were unable to deliver the expected outcomes on many occasions i.e. help explain the theory-practice gap, in these settings (maternity and stop smoking services) and with these populations (maternity and stop smoking services staff). However, using the four concepts to grasp the effect of the broader environment on the mechanisms and active ingredients was a struggle; for example, clarifying how supporting 'the work' at a meso and macro level affected feasibility and fidelity at the micro level remained obscure. Without this further dimension, I suggest that when applying NPT, I remain unable to confidently predict sustainability and transferability. Chapters 7 & 8 provided the information to demonstrate how - and to what extent - NPT explains the theory-practice gap and the role of fidelity. Together with Chapter 6, they set the foundation for the discussion, conclusion and recommendations that follow.

PART 4

Part 4 consists of Chapters 9-11 (Discussion, Conclusion, Contribution to Knowledge and Recommendations). In this section of the thesis I discuss the findings in terms of the research questions, repeated below:

Research questions (RQs)

1 To what extent does the NPT framework successfully allow:
a) identification and
b) elaboration
of the process of normalisation of a complex intervention?

2 To what extent does the NPT framework assist in understanding:
a) feasibility and
b) fidelity
whilst allowing interventions to be adapted to the needs of the complex systems in which they operate?

3 To what extent does the NPT framework assist in understanding:
a) sustainability and
b) transferability when scaling up to population level?

In the discussion I re-examine the latest developments in theorising normalisation in the light of these findings. I make clear the contribution of the thesis to knowledge and outline its strengths and limitations. Then I draw the narrative together in the conclusion. I make recommendations for the future use of NPT and suggest areas for theory and application development and future research and reflect on the implications for practice.

Chapter 9 DISCUSSION

9.1 Introduction

I will begin by identifying the key findings of this thesis and then make some general comments about the use of logic modelling and NPT during analysis, to contextualise the discussion. Next, I will discuss how the findings support or deviate from the literature and explore, using NPT, how the staff populations in the example are affected, and how the intervention supports pregnant smokers to overcome their specific barriers to quitting. Then I will discuss the role of NPT in investigating the implementation process, in the light of the literature.

Key findings:

1. NPT combined with a logic model offered a new perspective which a) clarified the feasibility of the intervention, and how amenable it was to being implemented with fidelity, and b) explained the underlying contexts at micro/meso levels and how they assisted or hindered implementation.
2. To understand what NPT tells us about the process of implementation when scaling up complex interventions, all aspects of the intervention need to be made transparent, including the context.
3. The context of the implementation at the macro (national) level was similar for all organisations but there was broad variation at the meso and micro levels, which had not been considered sufficiently beforehand, leading to questioning of the 'workability' of the intervention.
4. The intervention was designed with a standard context in mind, but as contexts varied widely, the intervention struggled to be sufficiently flexible to accommodate the variance.
5. Active ingredients and mechanisms were uncovered and found to be working to varying degrees; context complexity hindered many of them from becoming fully operational.
6. The degree of similarity with the existing services' delivery model affected the ability of staff to implement babyClear© with fidelity and had implications for sustainability and transferability.
7. To drive forward the implementation, active senior support within organisations, expressed in effective leadership, was critical.
8. Pregnant smokers experienced the intervention differently depending on the organisation they attended; even though it was intended to be a standard package.

9. There was inequitable provision, with greater support for some pregnant women to quit than others, due to variation in service provision.
10. There was evidence of a teachable moment for pregnant smokers and the importance of senior support to smooth the way for normalisation was apparent.
11. The new discourse was generally welcomed and supported by senior management and many frontline staff; and the therapeutic relationship was not generally damaged by the RPT or the intervention as a whole.

Analytical methods

Logic modelling and NPT are both becoming increasingly established (Papoutsi *et al.*, 2016; May *et al.*, 2018). The contextual barriers associated with the babyClear© implementation were illuminated through the use of a logic model (W.K. Kellogg Foundation, 2004) developed specifically for use in this thesis, in combination with NPT, which offered a theoretical framework that described the process whereby an intervention becomes embedded into routine practice (May and Finch, 2009). The logic model was derived from NICE PH guidance (2010) and the babyClear© pathway (Table 1-7) to visually represent the standard delivery model for supporting pregnant women to stop smoking. This logic model offered a basis to compare the various models that were identified within the data. Importantly, it also provided a framework to use with NPT, by which to interrogate the data and identify the contextual variables and their impact on each delivery model. These contextual variables were presented from a broad perspective, narrowing down to the local, and even the individual level. In Chapter 7 the findings are presented in terms of the mechanisms which were expected to reduce smoking in pregnancy, and Chapter 8 states the experiences of using NPT with logic modelling, to understand these mechanisms within the intervention. I will now discuss the specific group of women to whom this intervention applies, the findings from the implementation and the experience of using NPT, in terms of the literature.

9.2 Smoking cessation in pregnancy and intervention effectiveness

The findings from this study were consistent with existing evidence suggesting that supporting pregnant women to quit smoking is challenging for both women and staff (Chamberlain *et al.*, 2013). Although overall the number of pregnant women smoking at delivery declined during and after the study period (Bell *et al.*, 2018), it was clear that contextual barriers impeded a full and consistent implementation of the intervention. The eleven mechanisms of the intervention, designed to address the barriers to quitting smoking

in pregnancy, were found to offer a mixed, context-dependent picture. The service provided to women differed depending on the organisation they attended; even though it was intended to be a standard package. The reason for this was that contexts varied widely, both in terms of service systems and senior support. This led to inequitable provision, with greater support for some pregnant women to quit than others. This deviates from the literature, in that provision under trial conditions tends to be equitable; it was when the babyClear© intervention was scaled up and out that this issue arose, as discussed in this study (Bauld *et al*., 2010; Bryce *et al*., 2009; Chamberlain *et al*., 2013). The issue of improving take-up of services by this group of women tends to be the focus of design in these innovative interventions, rather than making the intervention fit the organisational or macro context; however, understanding the process of normalisation is the niche for NPT to fill (Bauld *et al*., 2010; Bryce *et al*., 2009; Chamberlain *et al*., 2013; May *et al*., 2016).

The demographic picture of women who continue to smoke in pregnancy is one of social deprivation, smoking as a family norm and low educational attainment, and they identify benefits accruing to them by continuing to smoke (Lumley *et al.*, 2009). Continuing, perceived benefits of smoking (which existed prior to the pregnancy) include bringing comfort, nurturing family and friend relationships, acting as a stress reducer and a coping mechanism (McBride *et al.*, 2004; Lawrence and Haslam, 2007; Flemming *et al.*, 2015). They may not have been considering quitting, however, pregnancy brings with it a heightened concern for their own health and that of their growing baby, increased interaction with HCPs, and public stigma associated with SiP, all of which create dissonance with their perception of the benefits of continued smoking (Barker *et al.*, 2002; Bryce *et al.*, 2009; Lupton, 2012; Borland *et al.*, 2013). This brings a 'teachable moment' and therefore, senior management support has been shown to be vital to capitalise upon this opportunity for behaviour change, by systematically prioritising the intervention, cutting through barriers and facilitating the changes (McBride, Emmons and Lipkus, 2003; NICE, 2010; West and McEwen, 2012). Evidence of a teachable moment and the importance of senior support to smooth the way for normalisation was apparent in this study's findings.

There was staff concern that the focus on individual behaviour change, did not address the broader social determinants, which are often present in pregnant smokers' lives, which left some staff feeling unable to offer holistic support. This is recognised in the literature, which reports on interventions designed specifically to address this issue (Bryce *et al.*, 2009; Mejdoubi *et al.*, 2014; Ormston *et al.*, 2015). The pathway goes some way towards meeting this concern because it favours enhanced support for pregnant smokers beyond the recommendations of NICE PH guidance (2010); however, follow up systems varied. Some

had philosophies underpinning them more in line with the intervention i.e. closer support, which made them easier to implement, however, others did not. The standard design was described in the logic model but the contexts lacked flexibility, which made it harder for staff to adapt it to the situations they faced, and ensure women received the support they required. Systems and services were rarely sufficiently well integrated to enable a smooth pathway, and there were unexpected capacity and resource issues. Therefore, the active ingredients and mechanisms were unable to function synergistically, and pregnant women did not receive the full, anticipated benefit of the intervention. This finding regarding the importance of making the theory of change (ToC) transparent and testing its feasibility before the implementation, so that outcomes are met, is consistent with MRC guidance (Moore *et al.*, 2014).

The new discourse was generally welcomed and supported by senior management, and many frontline staff integrated it into their practice to varying degrees; however, it continued to be questioned, with some staff remaining unconvinced. This offered a threat to normalisation, as applying NPT clearly points to the importance of coherence and cognitive participation, which act as harbingers of successful implementation (May and Finch, 2009; May *et al.*, 2018). The literature is clear that strong leadership is necessary to increase acceptance of change (Greenhalgh *et al.*, 2004). However, strong leadership was not always evident and pregnant women did not always receive the full package, including the RPT, which was one element of the intervention.

This was not only related to leadership; it was also affected by logistical barriers, however some leaders were more determined than others to ensure it worked. The importance of leadership, especially to overcome barriers, is well-documented (Waring *et al*., 2018). The RPT was reported as especially difficult to normalise. Staff who carried out the RPT mostly thought it had the intended effect, but it required a different approach, which some staff struggled with, as they perceived it as a threat to the therapeutic relationship. However, data analysis showed that the therapeutic relationship was not generally damaged by the RPT or the intervention as a whole. Nevertheless, maternity staff feared that it would be, which is a view consistent with the literature (McLeod *et al.*, 2003; Lawrence and Haslam, 2007; Baxter *et al.*, 2010; Everett-Murphy *et al.*, 2011; Beenstock *et al.*, 2012). Therefore, although analysis supported the new discourse and the RPT approach, these mechanisms were not available to all pregnant smokers. The findings that this was due in part to a lack of leadership in some settings, which was compounded by other contextual variables, such as incompatible systems, is consistent with the literature.

The analysis is clear that variation at many levels impeded the implementation and – observationally - impoverished maternal and fetal outcomes. While the evidence from NICE PH guidance (2010) suggests that the mechanisms themselves could be effective, they were not easily workable on many occasions. Therefore, although there were some successes, the number of barriers to enhancing the pathway meant that women did not always receive the integrated support that would give them the greatest opportunity to quit smoking. The literature agrees that women who continue to smoke during pregnancy require services that are led well and provide extra, evidence-based support to quit, and organisational contexts that optimise the work of the intervention (Bryce *et al*., 2009; Greenhalgh *et al*., 2004; NICE, 2010).

9.3 Role of NPT in investigating the implementation process

Although the basis for babyClear©, NICE PH Guidance (2010), drew together all the evidence to date, this guidance was not embedded and did not comprehensively influence practice in the North East of England (Beenstock *et al.*, 2012). The thesis initially arose from observation of this pattern, that complex interventions in public health, such as babyClear©, devised from high-quality, trial-based evidence, in practice often fail to achieve expected outcomes and impact in their standard form (O'Cathain *et al.*, 2015; Greenhalgh and Papoutsi, 2018). This theory-practice gap is not new, and many interventions have been posited to bridge this gap (see section 2.6-2.7); however, more recently an innovative theoretical approach has been developed (NPT) to tease out the barriers and facilitators to normalisation of a new practice (May *et al.*, 2009). The implementation of babyClear© in the North East provided an ideal opportunity to explore the usefulness of this theory. The aim of the thesis therefore was to examine the utility of NPT in understanding both this gap and the challenges to implementing evidence-based, complex, public health interventions.

The findings relating to NPT are discussed under the following headings:

- Importance of NPT in a positivist research environment
- Identifying and elaborating the implementation process
- Understanding feasibility and fidelity
- Understanding sustainability and transferability
- Role of mixed methods
- Challenges when applying NPT
- Novel use of NPT with a logic model

9.3.1 Importance of NPT in a positivist research environment

The findings chapters show that when babyClear© was introduced it could not be implemented as easily as envisaged. There were wide variations in what was implemented and how it was accomplished; in some locations the package of measures was not fully in place by the end of the evaluation. The findings revealed that the effect of a positivist research environment on understanding the implementation process meant assumptions had been made, for example:

- A standard SDM was assumed to work (rather than elaborated) by the intervention developers or evaluation study designers
- A single environment and context was assumed by the trainers and those who commissioned them
- Mechanisms of impact were assumed and not made explicit before implementation.

The development of the intervention was known to be pragmatic rather than experimentally based. It brought together trials' evidence and combined multiple elements that had been found to work; but they had not been trialled or evaluated together or in different contexts.

Experimental methodologies by definition take a positivist approach and focus on determining causal attribution by linking cause and effect while attempting to exclude contextual confounders (MRC, 2000). Although Bonell *et al*. (2018) would argue that this epistemology is not inevitable, they accept that it is the way that RCTs have generally been applied. It has been argued that this perspective is unsympathetic towards understanding the implementation process (Hawe, Shiell and Riley, 2004; O'Cathain *et al.*, 2013). As the intervention had been introduced into several, similar locations in England, although not evaluated, it was assumed it could be scaled up and out across the NE region. However, the intervention was designed for a specific set of conditions, but it was found that the broader environments into which it was placed, and local contexts, varied widely.

There was no certainty during the implementation regarding the need for fidelity of the whole package or some critical elements, or the possibility for modification for different elements of the intervention. It was not fully understood how the mechanisms of delivery and impact worked, as this knowledge did not exist, so the intervention could not be translated for the various contexts. The importance of identifying these factors and processes is underlined in the MRC guidance (Moore *et al.*, 2014). Greenhalgh and Papoutsi (2018) maintain there is a deficit of flexible and adaptive study designs to clarify implementation processes and inform intervention adaptation. This evidence from the literature was supported on the frontline by staff who were quick to point out the practice challenges they were experiencing as a result

of this lack of certainty. The key finding, that active senior support and effective leadership were fundamental to the implementation, became most apparent when barriers arose, progress was slowed, and the way forward was unclear. Iles and Cranfield (2005) support this view when they describe how the type of leadership affects the culture of a healthcare organisation and the behaviour of its staff; enabling or disabling work to overcome these challenges and move onto full implementation.

The findings support the notion that qualitative data, collected from staff, and contextual data, has been missed when using experimental methods. Unpicking the context complexity and its impact on the normalisation process and outcomes is essential, and therefore a more equally balanced research approach is required when developing evaluation study designs and implementation processes; one that also values an interpretivist methodology. This position is supported by O'Cathain *et al.* (2013) and O'Cathain *et al.* (2015). Logic models, ToC and interpretive approaches are a way to understand this process of implementation, so that outcomes can be understood as well as measured.

In summary, NPT has been shown in this thesis to be applicable and usable alongside an effectiveness evaluation, and able to bring an interpretivist perspective. Indeed, thinking by some researchers is moving away from a primarily positivist view, towards embracing complexity where appropriate, seeing it as less of a problem that needs to be stripped away, and more as a valuable, inventive and productive contributor to successful outcomes (Pawson, 2006; Greenhalgh and Papoutsi, 2018; Kreindler, 2018; Coldwell, 2019).

9.3.2 Identifying and elaborating the implementation process

This section discusses RQ1 (To what extent does the NPT framework successfully allow: a) identification and b) elaboration of the process of normalisation of a complex intervention?). The discussion posits that there are three main strengths of NPT core concepts derived from the literature review, that give confidence in their ability to identify and elaborate the implementation process (see Chapter 3) and understand the key drivers of babyClear© outlined in Chapters 7 & 8. These strengths are:

- It is grounded in well-established theories
- It allows flexibility of application
- It provides an analytical framework.

These relate to the findings on the utility of NPT reported in 8.6 and 8.7.

Grounded in well-established theories

Following the initial thinking and ongoing development of a nascent theory is like going on an adventure. Chapter 3 presented the literature on the theory-base for NPT, noted its transparent process of emergence and how it was designed to address the gaps in trial methodologies (May, 2006; May *et al.*, 2007a; May and Finch, 2009; May, 2013a; May, Johnson and Finch, 2016). It concluded that it was grounded in well-established sociological and psychological theories, including ToC and Diffusion of Innovation (Greenhalgh *et al.*, 2004; W.K. Kellogg Foundation, 2004). So, when I found that NPT was effective in helping to identify and elaborate the process of normalisation of a complex intervention to reduce SiP, in terms of detailing the requirements from the context (see 7.6; 8.3-8.5), this was consistent with the theory base. Many other studies, cited in May *et al*. (2018, p13), have also taken this view. It was also consistent with process evaluation theory, as set out in MRC guidance (Moore *et al.*, 2014) and with current thinking, vis-à-vis the theory-practice gap, discussed in Chapter 2. This is an important finding; that NPT is grounded in well-established theories, is consistent with NPT's stated aim (see 3.2) and supports the aim of this thesis (see 1.5), thereby establishing that it satisfies the requirement for reliable, non-experimental approaches to clarify the implementation process and narrow the theory-practice gap (see Chapter 2).

Flexibility of application

The literature takes the view that theoretical approaches which can flex with the implementation are able to elucidate elements of the theory-practice gap (Orton *et al.*, 2017). This flexibility allows them to more fully understand, and therefore address the issues raised when implementing complex interventions (Orton *et al.*, 2017). Carl May set out, in his paper introducing NPT (2006), the expectation that normalisation would be more flexible than diffusion, as a concept, and relevant to many healthcare domains. He also anticipated that normalisation would be able to embrace local differences and the 'fluidity' and 'dynamism' of the implementation process (May, 2006). My findings are consistent with this stance and have established that this flexibility of NPT has been expressed in three ways.

Firstly, it has been highlighted in sections 3.5 & 3.7.2 that NPT had an inherent flexibility, in that it has successfully been used with a variety of populations and in various healthcare settings, complementing the findings of the two reviews on NPT (McEvoy *et al.*, 2014; May *et al.*, 2018). This thesis' analysis concluded (see 8.8) that maternity and stop smoking services staff and settings could now be added to this list of populations and settings.

A second aspect of this inherent flexibility relates to the time in the evaluation cycle when NPT might be applied. For example, it was endorsed in Moore *et al.* (2014) as being suitable to use summatively. This was reported recently as its most common point of usage (May *et al.*, 2018), which has been supported by this evaluation's findings. The prospect of using it formatively is an interesting possibility. It was not used formatively within this evaluation study, but the results suggest that this would have been beneficial in informing the intervention design and implementation plans. NPT was used during secondary analysis to apply the data to a logic model, which can be part of a formative or summative assessment, suggesting that it is suitable for use at both points.

Thirdly, in 3.7.2, it was shown from the literature that NPT had been applied in different ways analytically (e.g. directly to the dataset and/or post-hoc, thematically). It could be coded to the key issues (inductively), as was the case for our publication, Jones et al. (2019), where cross-cutting themes were identified. Or it could be coded to the core concepts (deductively) (e.g. Bamford *et al.*, 2014; Browne *et al.*, 2014) and used to create bespoke concept definitions (e.g. May, 2006; Gallacher *et al.*, 2011; Alverbratt *et al.*, 2014; May *et al.*, 2018), as in this study (Tables 8.1-8.4). This analytical design, therefore, aided coding and analysis by clarifying the exact meaning of each concept in ways that were relevant and specific to the data. This flexibility allows study designers and analysts to appropriate NPT and adapt it for use in their studies, although care must be taken to maintain its integrity.

In summary, this extreme flexibility was a notable asset when exploring the theory-practice gap using NPT, as it allowed for reflecting on and then extending existing evidence. This ability of NPT to flex was used in this study to answer RQ1 in three ways: with a variety of healthcare populations and settings; summatively in evaluation; and during analysis and reporting.

Provision of an analytical framework

MRC guidance (Moore *et al.*, 2014; Craig *et al.*, 2019) suggested NPT could be employed as an underlying theoretical framework for process evaluation, when used in addition to an experimental methodology, as a way of encouraging whole-systems thinking. The use of this NPT lens would then increase understanding of how implementation is achieved and in what environment i.e. it would allow the researcher to view the inner workings of the intervention and how successfully (or otherwise) it could adapt to the variable contexts (Moore *et al.*, 2014; Craig *et al.*, 2019). Senior management were in the position most likely to enable whole systems working; their active support was seen to facilitate implementation. However,

the findings show how context complexity, alongside organisational fragmentation and uncertainty, due primarily to commissioners prioritising political stimuli, acted against systems thinking. This created barriers to mechanisms, such as smooth feedback loops, operating on the frontline. This lack of whole systems thinking is a barrier recognised in the literature (Moore *et al*., 2014).

May *et al*. (2018) in their review, give examples of how different authors have used NPT to analyse their data in different ways. They present this latitude as a strength (May *et al.*, 2018), which is supported by this study's findings, both for me, as the researcher (see 8.6.2), and for participants. Therefore, staff participants, whose interview schedules were based on NPT core concepts, while not necessarily thinking in NPT terms, were able to grasp the crux of the questions easily (field diary).

There is also some evidence that NPT has been particularly useful when trial results have been perplexing i.e. benefit was expected from an intervention but not demonstrated (Clarke *et al.*, 2013; Clarke *et al.*, 2014). So, by using NPT to understand the process, Clarke *et al*. (2013; 2014) were able to uncover the reasons for the lack of benefit. Similarly, I have established in this study that the core concepts offer a ready framework and lens through which to identify patterns of activity (see 8.2). In the case of babyClear©, the initial evaluation did show benefit during the implementation period, according to the set outcome measures, but the demands of the intervention at a time of challenge in the NHS meant that in practice the long-term maintenance of these new patterns of behaviour was unlikely. It seemed more likely that corners would be cut, and costs trimmed, and without an indication of what was absolutely critical and what was simply desirable, services were likely to diverge again from a common model. Secondary analysis, in the thesis, highlighted other active ingredients, facilitators and barriers, when implementing the complex intervention to reduce SiP (such as a flexible environment) and made explicit what was only implicit from trials evidence of different elements, which is vital for understanding the process and promoting sustainability (see 8.7.2-8.7.3).

In addition, the theory had three other strengths: linearity, misfits and complexity (see Tables 8-8, 8-9), therefore increasing its robustness. Linearity between concepts (i.e. coherence before buy-in, buy-in before action, and appraisal after action) helped understanding of the progress of implementation through the process and where and why it was halted (see 8.6.2-8.6.3). May *et al*. (2018) recognised that many studies preferred a linear interpretation and that this was associated with the overall study design, namely those interested in implementation; however, those that focused further along the timeline, on embedding and

integration, were able to comprehend a more iterative application. This suggestion is supported by the findings of this thesis.

Another strength, misfits, referred to those factors arising from data which were unexpected, that did not fit well with the original protocol and/or were not in the logic model (see 8.6.2). NPT was able to handle these in this study and reflect on their effect on normalisation. This was made easier by clarifying and coding data outside the logic model using core concepts defined from the data. This method of application of the conceptual framework was less strict, i.e. adapted to the study, supporting greater inclusion and therefore increased explanatory power (May *et al.*, 2018). Other studies have noted this issue e.g. Brooks *et al*. (2015) and dealt with it through discussion with the analytical team; however, for a PhD study the student works independently under supervision, so the team aspect is minimised. In addition, reviewing the ToC and introducing some of the complexity into the logic model at a later stage may be a way to address these unexpected misfits, if using this approach is integrated into the study design (Coldwell, 2019).

Lastly, the complexity of the environment required a nuanced theory like NPT that successfully allowed for variation, comprehended the organisational context and could adapt to it (May *et al.*, 2018). For example, Hoddinott *et al*. (2010) has argued the importance of a 'can-do culture' and Escoffery *et al*. (2018) has identified the importance of intervention adaptability during any implementation. However, I found that NPT, although it has the conceptual potential to embrace this complexity, in practical terms, during analysis, it was not possible to weave the macro level context with the organisational and team/individual level contexts. This may be connected with the study design; for example, in future, data could also be collected at macro and meso levels using different sources (e.g. documentary) and analytical methods (e.g. process mapping) and different interview questions (e.g. focusing on culture).

Therefore, I concluded that NPT was unable to fully embrace all aspects of context in this study, which limits how well its impact on the process can be understood and dealt with. Bearing in mind that NPT was designed with context in mind (May and Finch, 2009), this was a disappointing finding but not entirely surprising, as context is such a multi-layered, all-encompassing issue. This is a finding I refer to in the limitations section. May *et al*. (2016) extended NPT (eNPT) in recognition that this is a challenge, and although the theory architects have always been aware of the importance of context, they have focused this particular paper on addressing this challenge as part of the development of NPT.

The capacity of NPT to predict normalisation in the evaluation of babyClear© was limited by the study design, which reduced its ability to grasp the macro environment into which change i.e. the intervention, was being introduced. During thesis writing a paper was produced by May *et al*. (2016), as mentioned above, that does develop the initial theory in relation to context, but this study concludes that without an alternative protocol, eNPT still misses the effect from a) issues associated with organisational culture and b) from beyond the organisation.

In summary, answering RQ1, the theoretical base and flexibility in application and analysis enabled NPT to be used confidently to identify and elaborate the implementation process in detail. Many of these points were complemented in the recent review of the published evidence to December 2017, by May *et al*. (2018), who concluded that NPT "identifies characterises and explains mechanisms that motivate and shape implementation processes … using NPT can effectively assist in the explanation of the success or failure of specific implementation projects" (p1 of 27). The main area of divergence is the discussion on context, which is discussed more fully in 9.3.3. This may have been partly due to the limitations of the data collected, but also reflected the academic struggle to use NPT to comprehend context at all levels.

9.3.3 Understanding feasibility and fidelity

This section discusses RQ2 (To what extent does the NPT framework assist in understanding: a) feasibility and b) fidelity whilst allowing interventions to be adapted to the needs of the complex systems in which they operate?). Findings discussed in this section are set out in 8.7.1-8.7.7. I found the key to using NPT to understand feasibility and fidelity was in combining it with a logic model. Therefore, by allowing the determinants of feasibility and fidelity to be stated, this novel approach allowed detailed and practical guidance - that had not previously been identified prior to the secondary analysis for this thesis - to become available. Logic models are based on the idea that there exists, within every intervention, a ToC, and that it is necessary to understand the causal assumptions associated with the change to realise the intended outcomes (W.K. Kellogg Foundation, 2004; Moore *et al.*, 2014; Craig *et al.*, 2019).

As discussed in Chapter 4, there has been an ongoing debate in relation to how these assumptions often remain implicit but need to be unearthed and made clear if interventions are to be feasible. Researchers need to be able to identify fidelity issues to feed back to implementers and clinicians so that they can act. It has been argued in this thesis that

clarification of assumptions is of fundamental importance, if normalisation is to be achieved, and the contribution of NPT in revealing this process requires further investigation.

The need to retain the programme logic when making adaptations has already been evidenced (Escoffery *et al.*, 2018). In my study, the programme theory has been expressed retrospectively in a logic model, then analysed using NPT (Figure 5-1; Figure 6-3). NPT core concepts integrate well with a logic model: 'collective action' closely reflects logic model outputs; the core concepts 'coherence' and 'cognitive participation' highlight what promotes or hinders that action and informs understanding about how and why the mechanisms of delivery and impact do (or do not) work as well as expected.

As suggested in 8.2, NPT offers a framework to explore this interaction of factors in the implementation process and the potential for normalisation i.e. the feasibility of implementing it with fidelity to the point where it becomes routine. A discussion follows on how using NPT aids understanding of the implementation process, under the following headings:

- Feasibility, fidelity
- Explaining mechanisms of impact
- Explaining structure and culture of the organisation
- Explaining context

Feasibility, fidelity

A key finding of the study indicates that by introducing a novel analytical method (using logic modelling and NPT together), NPT could be used to explore feasibility and adaptability, and comment on fidelity, and therefore inform implementation of the example intervention (see 7.7). It was possible to take the active ingredients and identify where the intervention and/or implementation process could be adapted. I attributed this to an easy synergy between logic modelling and NPT which allowed them to be used together. NPT as a lens – unlike trials – can therefore be used, I suggest, to consider context, to identify mechanisms of impact, to work with complexity and is flexible enough to complement and integrate with a natural experiment; all these attributes have contributed to its utility.

This fits with the growing realisation that the environment and local context into which interventions are introduced, and the people who deliver them, have a profound effect on the intervention's ability to be implemented i.e. its feasibility (May *et al.*, 2007b; Rycroft-Malone *et al.*, 2010; Brand *et al.*, 2019). Both in the literature (see 2.3) and in this study (see 8.7.4) feasibility was found to relate to understanding a) the importance of change at every level, b) the mechanisms by which change operates and c) the interaction between individuals,

systems, mechanisms and environment. This is consistent with Coote *et al*. (2004), who state that 'investigation of the organisational, practitioner, and community characteristics which underpin successful implementation, and define conditions for best practice' (p197-8) is required to determine issues of feasibility and fidelity. Not only does implementation of an intervention need to be feasible but it must answer for fidelity also, that is, how closely it can be delivered to the intended standard (Moore *et al.*, 2014).

All elements of the babyClear© pathway were found to be feasible, where the mechanisms and active ingredients identified in Chapter 7 were available. However local contexts were often less than ideal, and therefore implementation became less feasible (see Chapter 8). The focus of the implementation changed, from putting into practice new skills, to creating systems that allowed the new ways of working to operate. A more detailed look at NPT and mechanisms of impact follows.

Explaining mechanisms of impact – including active ingredients

Explaining the mechanisms of impact was found to be a strength of NPT. Therefore, I was able to analyse the thesis' intervention example data to explain the specific requirements of the process, and guide maximisation of opportunities for normalisation of the intervention (see Table 8-12, 8-13). For example:

1. The feedback loop was often incomplete e.g.
    - Pregnant women arrived at SSS but their CO reading taken in maternity services was not known, or vice versa, they attended a maternity appointment and their progress with quitting smoking with the SSS was unknown.
    - Maternity staff did not receive an update on the outcomes from their efforts, such as, any change in engagement levels with SSS or quit rates by the women in their care.

This rendered the active ingredients relating to feedback inoperable and failed to trigger the whole systems approach mechanism, to bring about the desired outcome.

2. There were shortcomings in taking the necessary steps towards normalisation identified in the core concepts (coherence, cognitive participation, collective action and reflexive monitoring) e.g.
    - Senior leaders in some organisations were actively enthusiastic and made a way for new practices to be introduced, whereas in others their attitude was less enthusiastic and more problem-focused.

- Some midwives did not see that babyClear© brought anything different and resigned themselves to the impossibility of changing the behaviour of women smoking in pregnancy beyond what was already being done; whereas others recognised that babyClear© offered new opportunities to address this issue.

NPT was able to draw out these variations in practice at team and organisational levels, differentiating the intervention from usual care and identifying factors relating to the integration of services.

Identification of active ingredients is a significant achievement, as they are often difficult to identify in behaviour change evaluations, as compared with pharmacological trials, which is where the term originates (McCleary *et al.*, 2013). This is because "... intervention success is often dependent on the expertise of the intervention providers" i.e. not on a chemical ingredient, but a much more nebulous and variable factor (McCleary *et al.*, 2013). Grant *et al.* (2017) identified active and less active ingredients in their process evaluation which ran alongside a trial. Interestingly they discriminated between how and when ingredients are active, which might be a suitable topic for further exploration (Grant, Dreischulte and Guthrie, 2017) and indeed, is a concern of realist approaches (Pawson and Tilley, 2004). However, the literature around non-pharmacological, active ingredients is limited and McCleary *et al.* (2013) would contend that further exploration of them has been hampered by a lack of standardisation of terms.

In summary, by using logic modelling and NPT together, it was possible to clarify in detail the mechanisms of delivery and impact and active ingredients and, therefore, open the black box of the process of change, to reveal, to some extent, how the intervention and implementation worked. This has been a concern expressed in the literature over many years (Craig *et al.*, 2008; Craig *et al.*, 2009; Moore *et al.*, 2014).

Explaining structure and culture of the organisation

It was clear from the data that organisational structure and culture were key determinants of normalisation. An organisation's culture that facilitated implementation was described in the analysis as one that 'embraced change' and was 'flexible and adaptable'; whereas one that did not, was described as 'resistant' (see 7.6.8). The data showed that senior managers acted in ways consistent with the organisational culture i.e. proactively or reactively. In some cases, it was clear from the data that senior managers were not just responding to the direction of the culture but were also setting it, an observation supported by Iles and Cranfield (2005). This links with the key finding regarding the importance of senior support

and leadership to enable the implementation. This was underlined by the main finding from a systematic review by Gifford *et al*. (2014) about the role of managerial leadership in moving research into use i.e. that manager-staff dyads are highly influential in translating research evidence into action.

Iles and Cranfield (2005) write convincingly about individual, reactive and proactive/mature and immature, responses when someone perceives a challenge. A proactive response tends towards a positive, can-do attitude, and a reactive one to the converse (Iles and Cranfield, 2005), both of which were apparent in the data. Similarly, Greenhalgh *et al.* (2004) reflect on Rogers' (1962) ideas regarding the speed at which a new idea is adopted, depending on the organisational culture. These individual responses to perceived challenge, how they are perceived by others, and their effect within the organisation, depend on personal position and character (Iles and Cranfield, 2005). This juxtaposition of the individual and the whole system neatly depicts the inter-relationship between the micro and macro context in the literature; however, I found that this was not a focus of NPT. NPT sees activity in terms of teams and departments at the meso level, rather than individuals at the micro level (May, Johnson and Finch, 2016).

Normalisation is about changing cultures, which includes changing the way people think and what they believe (Iles and Cranfield, 2005; May and Finch, 2009). In the study, facilitating factors were identified when the example intervention was seen as aligning with personal beliefs e.g. new analysers perceived as beneficial (see 7.6.1), high level of buy-in to the 'quit completely' message by organisations and staff (see 7.6.4). Therefore, where the converse was apparent, beliefs became barriers (see 7.6.1, 7.6.4). For example: the reaction to implementing the RPT illustrates organisations' differing cultures i.e. their position when faced with a challenge (see 7.6.8). Willis *et al.* (2016) state that it is necessary to work with organisational cultural beliefs to bring about cultural change. Therefore, it is suggested from the literature in section 4.2 that an individual's ontological and epistemological position influences their views, behaviour and understanding of how to approach an issue. Application of NPT accepts this view; the core concepts, coherence and cognitive participation, are intimately connected with these beliefs and their influence on the potential for normalisation (Table 3-6).

Structures and cultures provide elements of the context of implementation, which are more fully discussed below. Although NPT concept definitions refer to context, they focus on frontline delivery, but organisation literature (see 3.5) talks about many aspects of the organisation and its culture which are played out on a broader stage. For example: a specific

lens might be person-centredness, as proposed by McCance & McCormack (2017), but these therapeutic relationships are underpinned by a wider culture of valuing and empowering the individual. However, using NPT to analyse the data focused on the micro context. Leadership, is another example of an important element in terms of reaction to change; leadership style, power balances, social relations and attitudes towards risk-taking, all influence attitudes to innovation and are embedded within structures and cultures (Greenhalgh *et al.*, 2004; Iles and Cranfield, 2005). These were found, in this study, to influence all four NPT core concepts. Similarly, so does a narrative of empowerment or disempowerment, where people either own their responsibilities and take innovative decisions or abrogate them and tend to avoid initiating change (Iles and Cranfield, 2005). Even sub-groups within the organisation may have local cultures which influence attitudes to introducing change (Iles and Cranfield, 2005).

Organisations characterised by a developmental, open, learning culture are better placed to incorporate change (Jacobs *et al.*, 2013; Harvey, Jas and Walshe, 2015); therefore deliberately building a culture that delivers the organisational agenda is important. Structure, i.e. the framework within an organisation, such as management hierarchies and service systems, has also been identified as influential upon organisational reaction to change (Greenhalgh *et al.*, 2004). Structure and culture influence uptake of innovations (Greenhalgh *et al.*, 2004); therefore, the prevailing organisational structure and culture will make it easier, or harder, for employees to embrace or resist change, depending on what beliefs and activities are supported by them (Iles and Cranfield, 2005). However, the study found that organisational structures and cultures were not comprehended well by NPT in this instance.

In summary, organisational structure and culture are key determinants of normalisation. Supportive structures and open, learning cultures with proactive leaders and managers are much more likely to support change. Using NPT assists in understanding the influence of structures, what thoughts and beliefs underlie behaviour and how they interact with implementation during the process of change. In this study, this was limited to staff perceptions of local structures and cultures due to the study design and the capacity of NPT to comprehend all levels of context.

Explaining context

Organisational structure and culture strongly influence the context in which services are delivered (Greenhalgh *et al*., 2004; Iles and Cranfield, 2005). In Chapter 6 I described the multiple contexts surrounding the implementation of babyClear©. I also contended that the

contexts had been largely overlooked, with the consequence that it was unknown if the hypothesised mechanisms would be present or accessible, at each implementation site. Without these mechanisms the activities and procedures that were expected to realise the outputs, outcomes and impact were put at risk. My findings support the evidence in the literature, that there remains a gap in implementation science around the attention to context that is required when implementing change initiatives in healthcare with fidelity (Squires *et al.*, 2015a; Squires *et al.*, 2015b). Therefore, although context is important in relation to 'workability' and 'fit' because they will determine feasibility (see 3.4, 3.7.2), Chapter 2 argues that context has been overlooked by mechanistic trials focused on causal relationships and effectiveness. The findings in Chapter 7, concerning the variability of system contexts, neatly demonstrate this point. Coote *et al.* (2004) explain it this way: "A mechanistic or linear view of change can accommodate the idea of clear causal pathways between government policy, practical interventions, and measurable outputs and outcomes in communities. A complex view of change pays more attention to history, culture and relationships, and sees change emerging from whole systems as they evolve over time" (p50).

The characteristics of context identified by Coldwell (2019), in his reflection on 'the role of context in 'theory-based' evaluations' (p1 of 19), are sympathetic towards the view of Coote *et al*. (2004) and would concur with my findings. He sees context as active, organic and non-linear:

- Dynamic, changing over time and therefore potentially changing how they influence interventions;
- Agentic, creating not simply moderating change;
- Relational, acting both as context for and as outcome of the work of initiatives, and acting in concert with or against the work of the initiative;
- Historically located, involving change processes over a much longer time period than the initiative at hand;
- Immanent, acting through – and as an intrinsic part of – participants' responses to the programme, not external to it;
- Complex, leading to changes that arise out of complex change processes at different system levels that interact with programme processes.

(Coldwell, 2019, p11 of 19)

This broader contextual viewpoint is also seen in Pawson's work: realistic evaluation, with its central mantra – context, mechanism, outcome – which surfaces and embraces context as a primary factor (Pawson and Tilley, 2004). This is demonstrated by those using realist

approaches (e.g. Jagosh *et al.*, 2015; Kreindler, 2018), however, Brand *et al*. (2019) acknowledge realist evaluation's limitations in managing the levels of context despite their accepted importance.

NPT is designed to accommodate many aspects of this complex, whole-systems view and seeks to address this imbalance (May *et al.*, 2011b). Therefore, I accept within the thesis, the need for this complex view and the inherent importance of context and holism to gain it (see 2.8). As argued in Chapter 2 and supported by the findings in Chapter 7, context wields huge influence over the outcomes of complex interventions, and NPT is a theory that tries to embrace and make sense of its effect on the implementation process (see Chapter 3). From the time that NPT emerged, context has been recognised as an important factor to be incorporated due to its effect on 'workability' and during its development from a model, to a general theory, ideas about context have been explored (May, 2006; 2013a; 2013b). However in contrast to Coldwell (2019) and Coote *et al*. (2004), May et al. (2016) have envisaged context as something practical; it is framed from a trial-based, quantitative viewpoint, thus it becomes a problem to overcome. This study's findings would deviate from this view and are more in sympathy with Coote *et al*. (2004) and Coldwell (2019).

Context is a comprehensive term with many aspects e.g. physical environment, economic, social, political, historical, cultural, although precise definitions can be elusive (Greenhalgh *et al.*, 2004; Moore *et al.*, 2014; Willis *et al.*, 2016; Orton *et al.*, 2017). May *et al.* (2007a) define context broadly as 'the physical, organisational, institutional and legislative structures that enable and constrain, and resource and realise, people and procedures.' Therefore, models that explain processes are designed to work at different contextual levels. May and colleagues divide them into two types: 1) psychological/individual and 2) sociological/group, and place NPT into the latter (May *et al.*, 2007b). As a sociological model that works at a group level, the NPM spells out levels of context: interactional workability=micro, relational integration=meso, contextual integration=macro (May *et al.*, 2007b). The micro level is called the 'immediate social context'; the meso level is where the immediate and wider contexts 'encounter' one another; and the macro level refers to the 'external healthcare organisations' (May *et al.*, 2007b). The macro/organisational level is discussed by May *et al.* (2007b) and noted as 'crucial'. This point is supported by the analysis reported in Chapters 7 & 8, which suggest that it is insufficient for the frontline staff to just carry out the work, but that the macro and meso context are critical too, in enabling and sustaining the intervention.

Incorporation of the broader environment and its many contexts into explanations based on NPT was found, in this study, to be extremely challenging, an issue which is referred to in the recent review by May *et al*. (2018). The theory developers acknowledged from the start

that there are challenges in applying NPM/NPT in relation to how it deals with context (May, 2006; May *et al.*, 2007b). The NPM focused on the act of implementation whereas NPT is a collective, organisational, social theory, which explicates what is happening at the meso – group/team - level, with investigation at the macro level (May, Johnson and Finch, 2016; May *et al.*, 2018). This step-change was identified as problematic, while accepting that the NPM is limited in its application by design (see 3.3, 8.4). Therefore, it was found that prioritisation of the meso/micro context prejudices the data collection and analysis against the historical, cultural, political and financial context relating to whole systems and the organisational environment.

Franx *et al.* (2012) found that the micro level focus of data collection detracted from other contextual levels and overlooked the macro context and speculated that this could be problematic:

> "Another criticism of NPT is related to the point that May and Finch address: that NPT 'focuses on the work of embedding and of sustaining practices within interaction chains' (May *et al.*, 2009). This implies that the NPT constructs are mainly based on perceptions of people, which presents the risk of leaving some contextual factors beyond the scope" (p11 of 13).

This division between individual, group, organisation and broader environmental activity in relation to normalisation creates confusion because the theoretical boundaries are blurred, as acknowledged by McEvoy *et al.* (2014). Normalisation requires collective action for institutionally sanctioned interventions to become routine practice but simultaneously is founded upon individual actors' activities (May *et al.*, 2007a), thus weaving together internal and external environment and multiple contextual levels as discussed from the literature in section 3.7.2. May offers little distinction between levels (micro/meso/macro) when using the word 'context', even in papers published later in 2013, leaving decisions to the researcher when applying the theory (May *et al.*, 2009; May, 2013a; 2013b). Therefore, while potentially improving flexibility of use this might also leave explanatory gaps.

This study was designed in 2012, using the then current MRC guidance (Craig *et al.*, 2008; Craig *et al.*, 2009); interview topic schedules were based on the latest core concepts (May *et al.*, 2009). There was no suggestion that data collection was to be conducted with policymakers or at times other than during operationalisation. Therefore, this design resulted in a greater focus at the micro or meso – rather than macro - contextual level during data collection. Macro level data were collected as supplementary notes in a field diary. Examples

of these contextual issues include varying systems, structures and cultures, reducing budgets, frequent restructuring, uncertainty, pressure to perform to specific measures and attitude to innovation (see Part 3). The initial analysis and formation of early findings, perhaps unsurprisingly, viewed Collective Action as applying only at the point of operationalising the intervention and normalisation as a linear process.

On reflection, during the writing of this thesis and redefining the core concepts from the data, it became clear to me that although all levels of contextual issues are covered by sub-groups within Collective Action, a gap remained in the study data. In Collective Action, when all stakeholders should be working together to implement the intervention, the gap that was exposed was the lack of data collected focusing on the broader environment prior, during and post implementation (see 8.7.1). Data associated with micro/meso systems and cultures were included, but macro level issues were largely excluded from the coding, which focused on individual experiences.

This reflects one of the criticisms by Clarke *et al*. (2013) - highlighted in May *et al*. (2018) - 'an over-emphasis on agency at the expense of implementation contexts' (p18 of 27). Clarke *et al.* (2013), state that NPT, 'tends to place undue emphasis on individual and collective agency without explicitly locating this within, and as shaped by, the organisational and relational context in which implementation occurs' (pp12-13). May defends NPT from the criticism from Clarke *et al.* (2013) by saying that it is not designed to provide a 'theory of organisational structure or behaviour' and signposts to other theories that fill this niche (2016, p4 of 12). This is rather disingenuous and avoids accepting that there are difficulties when applying NPT, in comprehending the complete contextual picture.

Although some authors do not highlight this as an issue when coding, in my experience there did not seem to be a comfortable way to code details about whole systems and their inter-relationship with one another and the world outside the organisation, at the same time as focusing on micro/meso considerations (see 8.7.1). A good example of researchers who have achieved this harmony are Bouamrane & Mair (2014a), who have succeeded in describing a regional, complex system and intervention while using NPT as 'empirical grounding' (May *et al.*, 2018). They used process mapping to describe the broad environment at the macro and meso levels, then applied NPT core concepts to understand the impact on the facilitators and barriers to intervention development and implementation (Bouamrane and Mair, 2014a).

I would contend that the focus for the study by Bouamrane & Mair (2014a) was always at the national and regional policy level; thus, the data collected by them, as compared with Clarke *et al*. (2013) or for this thesis, included interviews with policymakers and intervention developers, as well as frontline staff. This then allowed the researchers to apply NPT to a broader dataset. Even so, to analyse the data at micro, meso and macro contextual levels, they conducted a process mapping exercise before a thematic analysis using the NPT concepts (Bouamrane and Mair, 2014a).

Another example of using NPT as a partial framework is reported in May *et al.* (2011b) where two large datasets, which had already been independently analysed, were integrated during an analytical process using NPT (May *et al.*, 2011b). The paper describes results that are 'informed' by NPT, that is, NPT was not directly applied to the original data (May *et al.*, 2011b). Indeed, an example is given of how NPT drew out the structural issues (macro), which they argue had a greater effect than individual leadership (micro/meso), in contradiction of some participants' perceptions, and offered a more holistic interpretation than studies using NPT alone (May *et al.*, 2011b; Blakeman *et al.*, 2012; Franx *et al.*, 2012). These are two of several ways that researchers have integrated NPT into their studies (May *et al.*, 2018), also see 9.5.3. Therefore, viewing NPT as a partial framework, e.g. for interpreting selected findings or in combination with other analyses, is one approach that avoids the need for completeness. Although, for rigour and dependability, care needs to be taken when adapting and combining NPT to answer researchers' questions, to ensure that it is consistently applied (Ritchie and Spencer, 2012).

May *et al*. (2018) suggest that their review paper has gone some way to addressing this issue of accounting for multiple layers of context. Using other theories with NPT, as May *et al*. (2016) and May *et al*. (2018) suggest, was not previously stated as an intention for the way it was used. Therefore, viewing NPT less as a standalone theory, and more as a theory to be used with others, subtly changes how I perceive it. In my mind, it closes some doors and opens others e.g. it implies that a broader theoretical knowledge would be required but equally it could be harnessed to other theories and approaches in multiple combinations.

Two apparent contradictions around context in the NPT literature have raised challenges to consistency when applying the theory and coding contextual data. Firstly, NPT developers have posited more than one definition of context. May redefines it in 2013, in terms of location i.e. 'multiple spatial, organisational, normative, and conventional locations' (May, 2013a). This suggests that it has always been a moveable, rather than fixed, term for May. Secondly, context has also been defined in one way, as a sociological/group theory, then

used in another. This was noted by McEvoy *et al.* (2014) in their review of NPT papers, that the majority report 'single-stakeholder perspectives'. This contradicts the original, broad, macro, system level definition of context in May *et al.* (2007a) and therefore, excludes these aspects, as alluded to previously.

These contradictions may largely be explained by the stage of development of the theory (May *et al.*, 2018). It has been under continual development since its inception (see Chapter 3). It is interesting that early users have tended towards interpreting individual perspectives with it (McEvoy *et al.*, 2014). May and colleagues, on the other hand, have explored using it in different ways, and more recently May has taken up this apparent divide (frontline-clinical, individual/organisational) when postulating eNPT (May, 2013b). He accepts that individual agents have the potential to significantly affect change, as much as collectives, and explores the boundaries between them (May, 2013b). He acknowledges that this is a journey of discovery and the interplay between social systems, individual agency and context requires further enquiry (May, 2013b). "Implementation, context and complexity" is the title of May *et al.* (2016)'s paper, published several years after data collection for the study example and during reanalysis for this thesis. May *et al*. (2016) wrestle with these factors, particularly in relation to 'real world' contexts and when scaling up and out (see 3.8). They point out that contextual factors are 'diffuse', they interact with the intervention and implementation, that macro contexts are endless and ill-defined (May, Johnson and Finch, 2016). It almost sounds like an apology when they say:

> … it is hard to accommodate the complicated and interdependent relationships between different structural elements of 'whole systems', or to track the pathways through which different macro-level actors and processes shape implementation contexts at meso- and micro-level …
> (May, Johnson and Finch, 2016, p3 of 12)

Previously, they note, they have had trial situations in mind when writing, with process evaluation alongside them, but now are thinking about implementation in general, which gives a sense of release and unbounded possibility to the reader (May, Johnson and Finch, 2016). Their paper moots two new terms, 'elasticity' and 'plasticity', regarding interventions dealing with the 'non-linear, emergent and dynamic' nature of implementation processes (May, Johnson and Finch, 2016). Therefore, this offers new ways to think about 'workability' and 'fit' and the characteristics required of an intervention to maximise its potential to adapt to all the contextual variables (May, Johnson and Finch, 2016).

In June 2018, when this thesis was almost complete, May *et al*. (2018) published their systematic review of published studies using NPT, which reinforced how the theory is not set yet and is still evolving, largely through a collaborative, iterative cycle of use, reflection, review, amendment and addition (see 3.8). The babyClear© example was typical in terms of the type of intervention where NPT has been used, although it straddles two types (service organisation/delivery and guideline implementation) and was concerned with translating evidence-based guidelines into practice. May *et al*. (2018) claim that all but one of their 130 included papers offered, '… evidence that implementation outcomes could be explained by reference to the mechanisms specified by NPT' (p14 of 27). This seems surprising bearing in mind the finding here that it was challenging for NPT to incorporate all levels of context within its mechanisms. Perhaps it overstates the case in terms of degree of inclusion by NPT; although the complex, emergent, multi-level nature of contexts was acknowledged (May *et al.*, 2018, p14 of 27).

So, this argument leads to the conclusion that the inter-relationship of context with other components/factors needs to be understood, so that its effect can be clarified. However, it demonstrates that although NPT can offer some explanation, it still requires development for researchers to gain greater clarity around the interplay between implementation, complexity and context.

In summary, in discussing RQ2 I conclude that NPT was able to reveal the feasibility of implementing the example intervention with fidelity, by using a logic model. The easy synergy between the logic model and NPT was fruitful in terms of considering contexts, mechanisms and active ingredients, so that appropriate adaptations to the intervention and implementation process could be made. The recent review, published by May *et al*. (2018), helpfully has drawn together many of the papers reporting studies using NPT to date. It points out that the third phase of theory development has focused on context, as set out in two papers May (2013a) and May *et al*. (2016). However, this discussion suggests that further development of NPT is still required to fully address contextual variables at all levels, so that the detail of their impact can be understood, amendments to intervention design incorporated and outcomes maximised.

9.3.4 Understanding sustainability and transferability

This section discusses RQ3 (To what extent does the NPT framework assist in understanding: a) sustainability and b) transferability when scaling up and scaling out?). The important aspects to consider are the capacity of NPT for explanation of outcomes and

knowledge translation. Sustainability and transferability continue to challenge implementers of complex interventions. One reason is the nature of trial-based evidence (Chapter 2). NPT was designed to counter this challenge (May, 2006). The literature shows that NPT can be used for process evaluation, including frameworks for overall interpretation and/or more specific data analysis, application to various systems, settings and populations and is adaptable for use with different types of intervention and at different phases in the evaluation cycle (Chapter 3). Earlier in this chapter, how NPT has been used in this study to successfully support understanding of feasibility and fidelity and explain mechanisms of delivery and impact and active ingredients, was discussed (9.6.1). However, it has been argued from the findings that when NPT is used to account for context it has been less successful. All these components are necessary to understand why a complex intervention is/is not sustainable, transferable and scalable. Therefore, the discussion will now consider:

- Sustainability
- Transferability

Sustainability

The literature shows that there is a gap in the evidence for assessing sustainability when using NPT – few studies report on going back and checking how the intervention has developed; even though Finch *et al*. (2012) recognise the necessity of "continuous investment by individuals to carry action forward in time and space" (p2). There are exceptions (e.g. MOVE and STEPPING UP referred to in May *et al*., (2018)); however, Franx *et al.* (2012) identified this lack of appraisal as a weakness. Though it is worth noting that Aarons *et al.* (2014) hold that this lack of follow up is general to the field. This point is echoed in the babyClear© evaluation, where the data coded to reflexive monitoring is limited and there was no planned, long-term evaluation. Nevertheless, some factors that bear on sustainability were explored in the thesis and will now be discussed.

Knowing all the active ingredients, what is core and what is peripheral, makes it possible, according to Sitton-Kent (2016), to deliberately work towards operationalising them through coherence, cognitive participation and collective action; which will promote normalisation, sustainability and delivery of outcomes. In terms of sustainability of babyClear© the active ingredients included: senior support, engagement, resources, prioritisation, feedback, integration between services and a flexible response to change or systems that accepted the intervention. Therefore, where they were present, there were promising signs that sustainability was more likely, supporting the view of Sitton-Kent (2016).

Mechanisms and active ingredients that had not previously been recognised affected the potential for babyClear© to be sustained. I found that to activate them the focus had to move from upskilling, to system alteration, but this had not been recognised as an issue; so, it was not hypothesised from the outset, nor was the detail of its operationalisation outlined. Consequently, during training staff reported being unclear about if and how the intervention was supposed to work and how it was to be implemented in their context (see 8.4-8.5). Therefore, without a detailed plan of the ToC and how it was to be applied, the intervention became less sustainable, a finding supported by Kellogg *et al*. (2004).

Closely allied with normalising structures is the culture, which includes attitudes to change and innovation, which are especially relevant to sustainability (Greenhalgh *et al.*, 2004) (see 9.6.3). When the study data were explored, it showed that there were mixed views around coherence of the different mechanisms e.g. performance of the new CO analysers (see 7.6.1), trade-offs involved in opt-out referral (see 7.6.2). There was also cognitive dissonance when asked to adhere to a new protocol without the systems to support it e.g. quicker referral with more frequent contact even though the SSPS is unable to provide the requisite service (see 7.6.3, 7.6.5, 7.6.7), clinic systems whereby it is difficult to introduce the RPT (see 7.6.8). The literature supports the finding that culture at this point is critical, therefore, in settings that had a can-do culture, where the leaders responded pro-actively, change was facilitated, while others, with a more reactive approach, were slower to adopt the new ideas (e.g. see 8.5.8) (Greenhalgh *et al*., 2004; Iles and Cranfield, 2005).

The finding that sustainability of babyClear© is limited, due to the inflexibility and low adaptability of the standard package (see 3.5, 6.2, 7.7, 8.6.1; Appendix 11.2.2), is supported by May *et al*. (2016). For example: although training was valued for increasing coherence, skills and engagement with babyClear©; analysis of observations also highlighted that the sessions would have benefited from being tailored to each locality, in ways that did not threaten standardisation, and addressed how differences in protocol were to be applied and what changes would be expected of midwives / MCAs within the context of their existing systems.

The findings regarding operationalising the package of measures show that the sustainability of babyClear© was challenged when individual elements were insufficiently flexible. Specifically, the requirement for a midwife to deliver the RPT and the restructuring and re-commissioning of SSPSs were major barriers to sustainability at the time of the evaluation. This characteristic of an environment was called ‘elasticity’ by May *et al*. (2016) (see 3.8). A high level of elasticity is a known requirement for success, and is allied to identifying the

programme theory, mechanisms of impact and active ingredients (Moore *et al.*, 2014; May, Johnson and Finch, 2016). My findings strongly support the view that increased elasticity improve the likelihood of successful implementation, e.g. existing systems rejected the shape of the standard package, which was unable to mould itself to fit, creating long delays in implementation.

BabyClear© was found to require specific follow-up protocols, integration of services and availability of specialist staff, but these were not universally provided. Organisational changes were required to bring them about. A common obstacle to introducing change was the need for extra resource at a time of austerity. Knowing this was an issue, some measures had been introduced as part of the package, such as providing CO analysers and training at no cost to the provider organisations. However, active, creative thinking by senior management was still required to alter systems and sustain the intervention. Therefore, this inflexibility of the package, compounded by the lack of recognition that meso/macro system change was required, reduced sustainability overall.

This opacity in terms of the initial ToC, and consequent uncertainty regarding how and what to adapt during implementation, combined with a lack of plasticity and elasticity, suggests that there are likely to be some ongoing challenges regarding sustainability. Work undertaken subsequently by Fresh NE and Public Health England across the Trusts, to provide an update on progress, supports this view (Metters, 2018).

In terms of using NPT to understand the likelihood of sustainability, I was unable to integrate this macro context of national, regional and local decision-making into the micro/meso level analysis. Therefore, it was not possible to fully embrace the influence of context and apply it to the complete implementation; consequently, use of the theory to judge sustainability was impaired (see 8.7.5); although May *et al*. (2016, 2018) would challenge this view. Going forward, it would be interesting to record and analyse the changing contexts and apply NPT to assess their effect on the intended outcomes. Perhaps using the factors identified by Schloemer & Schröder-Bäck (2018) to strengthen the role of NPT in knowledge translation and intervention transferability, namely: population, intervention, environment and transfer (PIET-T).

Nevertheless, recognising the partial success of babyClear© is supported by Sweeney-Magee *et al.* (2016, p10 of 11), who suggested that absolute fidelity may not always be necessary for an intervention to be effective, so long as it is sufficiently flexible. The long-term sustainability of babyClear© is still in question; however, recent positive SATOD trends

(see 1.8.2) suggest HCPs may have adapted it successfully to local contexts. Therefore, accessing the extensive literature associated with organisational culture and change management may be a next step in developing and informing the use of NPT (Harvey, Jas and Walshe, 2015; Schein and Schein, 2017).

In summary, as confirmed by the wider literature, the intervention required elasticity from organisational structures, positive attitudes from local cultures towards learning and change, and plasticity from the mechanisms within it. These were all key to normalising and sustaining the intervention package. This thesis also recognises that using NPT to predict or explain sustainability has not previously been comprehensively reported and this study has not been able to fill this gap either. However, many of the key elements were interpreted during analysis and it is in understanding them, their flexibility and adaptability and their interaction with the various aspects of context, that sustainability can be maintained. Context, especially in relation to organisational structures, culture and resources, at every level, has been shown to affect sustainability; yet this thesis found that researchers using NPT to comprehend context was an issue, which leaves findings around the example intervention's future incomplete. Therefore, further work is required in this area of theory development, or possibly in the way it is applied by researchers. Similarly, although NPT was recognised as consistent with work on organisational culture and change management, benefits from working in combination with this research area require further investigation. NPT makes a significant contribution in facilitating elaboration of the normalisation process, but it appears weaker in terms of a) translating that knowledge to practitioners who will be expected to embed the intervention; and b) understanding or explaining some of the factors relating to organisational and managerial culture, the contexts that influence uptake and sustainability of change. Therefore, further work is also required in these areas to maximise sustainability.

Transferability

The intervention was presented as a standard package, with little elasticity, therefore, it was challenging to transfer, when the context differed, as it did in almost every locality. A position that would be supported by May *et al*. (2016). BabyClear© is transferable where the context is sufficiently similar to where it was devised e.g. includes a dedicated PH midwife, qualified and available in all clinics where there are pregnant smokers, and SSS that provide a specialist service with enhanced follow-up support. Understanding the primary context and the mechanisms of change, therefore, are vital components before introducing adaptations during transfer to new settings (Escoffery *et al.*, 2018; Schloemer and Schröder-Bäck, 2018).

This study has explored ways to improve transferability of the intervention example in several ways. Namely, by hypothesising the theory and mechanisms of change using a logic model, identifying other active ingredients, their barriers and facilitators, and using NPT to explain the implications (Part 3). In addition, Jones *et al.* (2019) outlines the cross-cutting themes, identified inductively through using NPT, in terms of the requirements for implementing babyClear©. On transfer, evidence-based interventions frequently require adaptation; this commonly occurs in the areas of content, context, culture and delivery (Escoffery *et al.*, 2018).

This study found that use of the logic model summatively, allowed for a deeper understanding of why and how these primary, contextual conditions were required. The assertion that NPT's utility is in creating this new knowledge, therefore means that, when transferring elsewhere or scaling up, issues can be prevented or dealt with, with more assurance. This point is supported by Schloemer & Schröder-Bäck (2018), who, while acknowledging that, "Transferability of health interventions is a complex concept," assert that it, "… needs systematic consideration of the primary and target context. It [transferability] should be anticipated before and evaluated after an intervention is implemented in the target context" (Schloemer and Schröder-Bäck, 2018). Therefore, this study's findings would concur that knowledge derived from the research needs to be translated for use during implementation and practice elsewhere and understanding the context thoroughly is fundamental to this endeavour (Bell *et al.*, 2018; Coldwell, 2019).

In summary, although NPT illumines part of the theory-practice gap associated with introducing trial-based interventions into a complex healthcare environment, it stops short of fully clarifying the factors associated with transferability. Therefore, this is an area for future research, to ensure that the intervention is transferred successfully.

9.4 Role of mixed methods

I have argued that both quantitative and qualitative data are required to create useful knowledge about implementing, transferring and sustaining complex interventions. However, the literature agrees that mixing different methods, data types and sources introduces questions about the purpose of using them together and how to mix them (Vogl, 2018; Yousefi *et al.*, 2018). There is a distinction between combining and integrating data, and also a need to identify at what stage in the analytical/ interpretive process the data comes together (Vogl, 2018). Therefore, these are all considerations for future study designs.

In the evaluation of babyClear© the different data types from the two main strands of the evaluation were generally kept separate, did not inform one another and were neither integrated nor combined. There was one, unplanned exception; the qualitative data was used post-hoc to develop some of the analytical variables to overcome gaps in the numerical data. However, I would argue that this was a much greater, missed opportunity as, potentially, using effectiveness and interpretive methods together could have improved the findings in other ways too, e.g. reduced delays in implementation (through a feasibility study) and increased sustainability and transferability (through the main study). Therefore, using data sequentially – rather than in full combination or integration - might have been appropriate during analysis and interpretation, which can still be defined as a mixed method, due to the level of inter-dependence in analysis (Vogl, 2018).

NPT has most commonly been used as a theoretical base for interpretive studies, primarily collecting qualitative data; however, it is grounded in the idea that social networks are important to normalisation (May and Finch, 2009; May *et al.*, 2009). Social Network Analysis is a method for looking at these networks that combines quantitative and qualitative data, suggesting therefore, that, NPT may be suitable for some mixed method study designs (Yousefi *et al.*, 2018). Publications are beginning to report some level of combining quantitative and qualitative data sequentially when applying NPT, using sources such as trial outcome data, surveys of job satisfaction and team climate and in-depth interviews (e.g. McIntyre *et al.*, 2018; Patel *et al.*, 2018). Therefore, the role and application of mixed methods with NPT is an area for future research, which will strengthen study designs and increase the effectiveness of interventions.

9.5 Challenges when applying NPT

The research questions ask, 'To what extent … the NPT concepts are useful?' In applying NPT, a subsidiary finding arose, that is: How easily can NPT be applied? i.e. a practical, rather than a conceptual, question. When applying NPT, four, overall challenges were noted:

- Adapting the terminology
- Overlaps between concepts
- Non-standardised application of NPT
- Linearity and iteration

A review of the origins of these challenges - found in the literature - and a more detailed discussion are in section 3.7; however, the key points are summarised below:
Adapting the terminology –

Applying NPT requires translation as the terminology was found to be inaccessible due to the phraseology and the definitions (Table 3-6). Therefore, the concepts and sub-constructs required translating and redefining before applying them to this project; a finding supported by other users of NPT (Gunn *et al.*, 2010; Atkins *et al.*, 2011; Sanders, Foster and Ong, 2011; Franx *et al.*, 2012; McNaughton, 2017; May *et al.*, 2018). The reason being that clearly bounded, standardised terms or phrases are important when communicating new ideas, to ensure that everyone understands them in the same way (McCleary *et al.*, 2013; Craig *et al.*, 2019; Walugembe *et al.*, 2019).

Overlaps between concepts –
Applying NPT requires boundary decisions as NPT constructs are close in nature and were found to overlap when coding data; however, some data fell outside the concepts altogether, as has happened in other studies (May *et al.*, 2018). Therefore, a systematic method to handle this issue is required.

Non-standardised application of NPT -
Consistent decisions need to be made as to how to deal with data which appears to relate to multiple constructs or none (McCleary *et al.*, 2013; Hooker *et al.*, 2015). Study-specific definitions were created for greater clarity and to promote accurate coding. This solution has been applied in other studies to deal with overlapping issues (Alverbratt *et al.*, 2014; Hooker *et al.*, 2015; May *et al.*, 2018). Therefore, where NPT is not comprehensive in dealing with the data, it promotes diversity in analysis e.g. invites application of alternative methods, but risks reducing rigour and missing or misinterpreting important findings (Ritchie and Spencer, 2012; Alharbi *et al.*, 2014; Aarts *et al.*, 2015).

A non-standard approach has led to variability in usage and reporting. Historically and practically reasons have been given for preferring one concept over another during application (Bouamrane, Osbourne and Mair, 2011; MacFarlane and O'Reilly-de Brún, 2012; Ehrlich, Kendall and John, 2013). Questions about sustainability and transferability cannot be answered without a consistent, comparative and comprehensive approach; neither can evidence be easily found when reviewing the literature if terms are inconsistent (McCleary *et al.*, 2013). Using concepts separately or differently is not supported theoretically, and therefore, novel ways need to be found to address this issue (May *et al.*, 2018) (see also 3.7.4).

Linearity or iteration - NPT can be interpreted either way

The developers encouraged researchers to apply NPT as they saw fit, rather than in a standard way (May *et al.*, 2018). Although NPT was developed as an iterative approach, designed to reflect the dynamic nature of intervention implementation, publications of studies using NPT since 2006 reveal that frequently it is used in a linear way (Sanders, Foster and Ong, 2011; Alharbi *et al.*, 2014; May *et al.*, 2018). Uncertainty about how to apply NPT, and the process of working through to the best fit, therefore, leads to intriguing discoveries, as in this thesis, while increasing the potential for dissonance and tension for the researcher. This idea is supported by May *et al*. (2018), who suggest that the challenges should be embraced as they can be used to stimulate theory development.

9.6 Novel use of NPT with a logic model

Logic modelling is a tool that has been used in many ways since its inception (see 2.5.1). It performs an important function when thinking through a project and explaining how it is expected to work. In MRC guidance (Moore *et al.*, 2014), logic models were mentioned as an example of how to work through the first component of a process evaluation: description of the intervention and its causal assumptions (see Figure 2-2). NPT was also recommended by the guidance as a theory that could be employed in process evaluation (Moore *et al.*, 2014).

There are some similarities between logic models and NPT; they are both primarily concerned with uncovering the implicit details of complex interventions, can both be used formatively and summatively, as well as for review throughout the implementation process and their categories are sympathetic to one another (see 6.3). Coherence and Cognitive Participation are like inputs, which are required to produce the output of Collective Action and the outcomes which are assessed in Reflexive Monitoring. Logic models and NPT inform understanding about how, why and how well mechanisms of impact work (see 6.3).

The starting point for the thesis was a lack of logic modelling in the study design; however, bearing in mind their similarities, it is a reasonable proposition for logic models and NPT to work well together. Both can be used flexibly, they welcome adaption to different settings, populations and topics within the health and public health fields (see 2.5.1). Therefore, this thesis argues that this tool has successfully been combined with NPT to answer some of the common questions about the process of implementation of complex interventions, including fidelity, feasibility, adaptability, sustainability and transferability; and has the potential for further application.

9.7 Limitations

The study identified some limitations of the methods when NPT was used to:

- Predict sustainability
- Predict transferability

NPT alone was unable to predict sustainability and transferability due partly to the data collected for analysis. For example: the lack of a pre-implementation logic model and the limited longitudinal element in the original study design, meant that unforeseen delays in implementation altered and further limited data collection opportunities. In future the use of NPT could be maximised if these omissions were rectified.

The study identified some limitations of NPT when exploring:

- Organisational culture
- Context for change
- Usability of the theory

The capacity of NPT to predict normalisation was limited by the study design, which reduced its ability to grasp the macro environment into which change i.e. the intervention, was being introduced. During thesis writing a paper was produced by May *et al*. (2016) that does develop the initial theory in relation to context, but this study concludes that without an alternative protocol, eNPT still misses the effect from a) issues associated with organisational culture and b) from beyond the organisation. Study data on sustainability and transferability were limited, a situation reflected in the published literature on NPT to date; however, it was found that NPT can identify factors that are likely to influence them i.e. what is needed to scale the complex intervention up, and out and continual progress is being made towards this goal (May, Johnson and Finch, 2016; May *et al.*, 2018).

There were also challenges to the usability of NPT. The findings in the thesis foreshadowed the assertions in May *et al*. (2018), which drew together the comments from other researchers, claiming that the terminology was not user-friendly, there were boundary and inequality issues when using the concepts and there was uncertainty about the iterative design. This is an area for ongoing reassessment and improvement.

There were also limitations to the doctoral study itself:

- Academic purpose
- By design

The study was carried out for an academic purpose; thus, it was limited in terms of accepting one view only, that of the student, and a focus on academic success rather than research for any other purpose (Rawnsley, 2018). Doctoral degrees require that the student studies alone and that the work they report is their own; although others may offer advice and opinion, it is an individual, learning experience (Rawnsley, 2018). Therefore, more experienced contributors may not have the final say - unlike when working in research project teams – risking more errors in the final thesis.

Qualitative methods, like all study designs, have some limitations (Bryman, 2012). They do not aspire to answer positivistic questions; they are concerned with experiences and personal perspectives (Bryman, 2012). The data are judged by trustworthiness rather than generalisability (Lincoln and Guba, 1985; Bryman, 2012). Trustworthiness can be developed by using methods such as triangulation, member checking and saturation, as used in this example (Lincoln and Guba, 1985; DePoy and Gitlin, 2005). These methods are designed to improve data quality (Bryman, 2012). Taking a reflexive approach, as here, is also considered to be an appropriate way to counter bias (Bryman, 2012).

The data used in the example were collected for a different purpose, giving rise to the possibility that it was inappropriate for the doctorate. The data collection tools and primary analysis were based on the theory under study; therefore, it is unlikely that additional questions would have been asked if the doctorate was the sole purpose of data collection. The doctoral research questions were devised after data collection, when the composition of the data was already known. More longitudinal data would have been preferable; however, the environmental contexts at the time meant that this was not feasible.

I was inexpert and did not know the best way to approach solving the research questions; I tried various ways to analyse the data. The analytical design therefore evolved and was not pre-planned. This was time-consuming and, in that sense, an inefficient method. Due to the time taken to complete the study - in part due to my substantive research role and undertaking the PhD study part-time - and the continuously evolving nature of NPT, papers were being published and changing the field at the same time as the work was being completed (Finch *et al.*, 2012; May, 2013a; 2013b; McEvoy *et al.*, 2014; May, Johnson and Finch, 2016; May *et al.*, 2018). This is always going to be a challenge in a developing area of research.

There were also limitations relating to the host organisation:

- Non-standard PhD

- Organisational restructuring

This application for a doctorate was based on continuing the promising work that was emerging from a funded project. The doctoral study was funded through my own financial contribution and Teesside University sources, an opportunity available to staff members. There was no specific funding for extra costs e.g. conference attendance, training etc., although application could be made through the usual university channels. Organisational restructuring and increased levels of staff turnover required extreme persistence on the part of myself and the supervisory team to complete the degree.

9.8 Strengths

This study has strength in terms of:

- Contribution to knowledge
- Timing
- Quality of supervision

The thesis offers new knowledge in three areas: theory application, process evaluation and clinically, in a fast-paced and changing field. Immediately prior to and during the study, several papers relating to development of the theory were published by its architects (Finch *et al.*, 2013; May, 2013a; 2013b; McEvoy *et al.*, 2014; May, Johnson and Finch, 2016; May *et al.*, 2018). Papers reporting on applying NPT to research projects continued to appear (see May *et al.*, 2018). This progress, while challenging, was also stimulating and motivating. It provided more 'meat' to digest; while suggesting that the study was timely and supported the hope that its findings would become part of the overall theory development.

Although working part-time on the thesis meant it would take longer to conclude, this circumstance also offered a greater opportunity to broaden experience while working on other projects and view other data through the lens of NPT. It offered time to think about and mull over the doctoral work for a prolonged period, in the context of disseminating the results.

Regular, monthly, supervision meetings throughout, with expert advice, ensured that steady, independent progress was supported, and learning promoted.

9.9 Conclusion of discussion

The findings of this research have been discussed in relation to how a smoking cessation in pregnancy intervention was implemented by maternity and stop smoking services staff, across a region of England, and the effect of the implementation on services, staff and pregnant smokers. The key focus of this thesis was to examine the utility of NPT, which, when combined with a logic model, was found to offer opportunities for understanding the active ingredients and mechanisms necessary to complete such an implementation, and undertake those processes successfully. However, I argued that data analysis showed there were barriers that impeded the implementation process, especially relating to the context of implementation, and that there are still academic challenges around designing studies that comprehensively address these impediments.

NPT has been promoted as a mid-range theory that provides a framework to aid understanding of normalisation and thereby smooth the working of these processes. I suggest that NPT, or a similar interpretive approach, is of equal value to experimental theory and methods; and offers a necessary perspective in improving implementation processes in complex public health interventions. Further, I found that NPT is strengthened by being used in combination with logic modelling and that they work synergistically.

The findings suggest there are areas where NPT would benefit from continuing to evolve. These include a stronger grasp of organisational culture, how it handles context, especially at the meso/macro levels, and the interplay between implementation, complexity and context. Further, I suggest, more work is required on using NPT to inform sustainability and transferability. There were some issues when applying NPT during analysis of the data which also require attention.

The trend arising from MRC guidance (Moore *et al.*, 2014; Craig *et al.*, 2019) and the implementation literature suggests that researchers will need to become more open to integrating methodologies and methods. Integrating a logic model and using NPT fits well with this trend. The study was limited by some attributes of the method and NPT, the nature of doctoral research and major restructuring within the host organisations. Nevertheless, the study was conducted at an opportune time and was able to offer some new, well-founded knowledge.

Chapter 10 CONCLUSION and CONTRIBUTION TO KNOWLEDGE

10.1 Introduction

There is evidence of a theory-practice gap when implementing complex public health interventions. In writing this thesis, I accepted the premise that explaining the mechanisms and active ingredients - within the process of implementing this type of intervention - would reduce this gap. NPT had been suggested as a suitable framework for examining this premise. I established from the literature that the prevailing research environment has not been conducive to interpretive methods and thought about how NPT might yet have an explanatory role. I brought in logic modelling to establish the programme theory i.e. how the intervention was expected to work, then contrasted it with what the data were telling me about how it had worked i.e. the practice. Then I used NPT to understand the differences between theory and practice. In this chapter, I will now summarise these points and conclude to what extent NPT has been useful in revealing and explaining the theory-practice gap. I will go on to identify the specific contributions of this work, the recommendations arising from it and the implications for future research and practice.

10.2 Conclusions of the study

The literature is clear that there exists a gap between theory and practice when relying on trials evidence alone. I have investigated the contribution of NPT, a social theory, in explaining this gap when implementing a complex public health intervention. The intervention was based on NICE PH Guidance (2010); what it lacked was a clear understanding of the process that would bring about the outcomes.

Normalisation, as an easy-to-grasp idea, made notable progress towards answering this challenge. However, I found that the public health research environment is not always ready for an interpretive theory like NPT; even though it has a strong foundation in established theories and offered an appropriate framework to consider the process of normalisation during implementation.

One strength of NPT is its flexibility. I used it formatively in combination with a logic model and summatively during analysis. I used a logic model to articulate the ToC, which was then compared with the actual implementation process. I also found NPT to be flexible enough to provide an appropriate structure for data coding, management and analysis. These methods allowed me to meet the aim of this thesis: to examine the utility of NPT in understanding the

theory-practice gap and the challenges to implementing evidence-based interventions. By using NPT, I was able to open up 'the black box', describe the implementation process and elicit the reasons why it was - or was not – carried out smoothly i.e. the intervention's 'workability' and 'fit'.

In turn this synergy between the logic model and the theory threw light on the mechanisms of delivery and impact, active ingredients, feasibility, adaptability and their effect on outcomes. This created the possibility for informing practitioners of the requirements for implementing the intervention successfully (Appendix 11.2.2); knowledge that would not have been known from a trial. These methodological choices were supported in the literature in that NPT has been integrated successfully into different research designs in various ways to improve the understanding of processes.

However, the main limiting factor that was identified was an inability, when using NPT, to comprehensively incorporate the multiple levels and aspects of context into the analysis. It has been argued by May *et al*. (2016) that the influence of context is not the focus of the theory. I would accept this argument and also concede that additional data were required in this study but, in addition, a method is still needed to account more fully for this important element, especially at a macro level. This has been acknowledged in a recent review of NPT papers (May *et al.*, 2018).

I would argue that there are also disadvantages to using NPT flexibly e.g. publication around use of the theory has been unsystematic and led to varying frequency of use of the different concepts, so the quantity of available evidence for each concept is unequal. Consequently it is not straightforward to directly compare the use of the different concepts and this unequal application can lead to misinterpretation of data and difficulty in predicting sustainability and transferability.

Other challenges to the use of NPT, identified in the findings, were translational. Employing different definitions for the same terms caused confusion, as has been reported elsewhere (May *et al.*, 2018). Theoretical terms, their definitions and boundaries required clarification and translation. This was overcome in the thesis by adapting NPT, e.g. creating study specific definitions and coding to multiple concepts if there was overlap. Where data fell outside the concepts, new themes were derived inductively. Adapting how the theory was used, while remaining consistent to the content of the core concepts, allowed it to meet the needs of the study and for the analysis to be completed. Thus, the translational challenges were addressed.

There were also practical challenges. These included incomplete cover of data and a lack of differentiation between the importance - strategically - of some contextual elements over others. Perhaps the most challenging practical issue was the tension between linearity and iteration when applying the theory; that although it is designed to incorporate a dynamic reality, it was confusing to apply.

Confidence in the sustainability and transferability of interventions, and the use of NPT in this regard, was discussed from the literature. Findings from the study agreed that evidence was lacking to support the notion that analysis with NPT could fully inform sustainability and transferability. Although, by combining with the logic model, a deeper understanding of the contextual conditions required was achieved.

I theorised from the literature that combining evidence from socially-based research with trials-based results, when planning and implementing a complex, public health intervention, would narrow the theory-practice gap. Specifically, that by applying NPT the success of implementation would be improved through an understanding of the normalisation process. In conclusion, I have established that the philosophy and practicality of using NPT, and the structure it provided, enabled the process of normalisation to be elicited. I suggest that an interpretive theory, such as NPT, should be routinely incorporated when implementing trial-based, complex interventions into public health systems.

10.3 Contribution to knowledge

10.3.1 Introduction

This chapter seeks to summarise for the reader the contribution to knowledge found in this doctoral study. Understanding complexity during the implementation of public health interventions is the concern of this thesis, so that their effectiveness is maximised. The thesis' basic contention is that, due to over-reliance on trial-based evidence for intervention designs, the active ingredients and mechanisms of delivery and impact are left implicit and complexity is largely overlooked (Moore *et al.*, 2014). This is experienced when implementing complex interventions and scaling up - i.e. within the same system - and scaling out - i.e. to other settings; in that interventions which are tested experimentally and appear to work, once they are brought into multiple, real-life contexts, frequently produce disappointing outcomes (Moore *et al.*, 2014).

To address this issue NPT has been applied in a new way which advances current knowledge in three domains:

- Theory application
- Process evaluation
- Clinical situations.

10.3.2 Theory application

The thesis covers five areas of new knowledge relating to application of NPT:

- Method (how to combine NPT with a logic model)
- Setting (location and type)
- Population (maternity and stop smoking services staff)
- System (organisation and service)
- Topic (clinical guidance).

The method is novel in two key ways. Firstly, this is the first time that NPT has been combined with a logic model and their ability to work in combination demonstrated. I found that what was understood from ToC and the logic model - about how the intervention worked - could be taken and re-examined using the lens of NPT. Comparison of the expected process and mechanisms of delivery and impact, with the actual processes in the implementation of a complex intervention, identified elements of the theory-implementation gap left by trials evidence. This was possible because the core concept 'collective action' closely reflected logic model outputs; the core concepts 'coherence' and 'cognitive participation' highlighted what promoted or hindered that action and informed understanding about how and why the mechanisms of delivery and impact did or did not work as well as expected.

The second way in which the method is novel is the redefining of the core concepts to translate and adapt them for use in the specific study. This process of translation facilitated their use in exploring NPT's utility. May *et al*. (2018) suggest that this challenge has arisen for others too, when employing NPT and using deductive analytical methods, however researchers have had to devise their own responses specific to the study. Further research would be required to see if the concept definitions could be applied outside this study.

The setting, population and system when applying NPT are also novel. This is the first time NPT has been used with stop smoking services, or with an intervention including both maternity and stop smoking services. It was found that the NPT concepts were sufficiently flexible and adaptable to apply them to maternity and stop smoking services settings and their staff. By using NPT, the process of normalisation of the intervention in these populations and settings was identified and elaborated. NPT has been used predominantly

in the NHS in England, as is the case here, and has only been used twice before in maternity services, both times in Australia in relation to domestic violence (Spangaro, Poulos and Zwi, 2011; Hooker *et al.*, 2015).

The topic, tobacco control, was a new area for which NPT had not previously been employed. It had not been used to look at an intervention with smokers or smoking behaviours. Nevertheless, using NPT allowed me to clarify the process of implementation of a tobacco control package of measures.

Similarly, this was the first time NPT had been applied to NICE PH Guidance 26 (2010), although it had previously been used to understand the process of implementing a range of other NICE guidelines e.g. management of chronic fatigue and chronic kidney disease, debt counselling for depression, primary care prescribing and osteoarthritis care (Blakeman *et al.*, 2012; Grant, Guthrie and Dreischulte, 2014; Ong *et al.*, 2014; Bayliss *et al.*, 2016; Gabbay *et al.*, 2017; Grant, Dreischulte and Guthrie, 2017). Bringing together an intervention (babyClear©), which was closely based on NICE PH Guidance (2010), and the lens of NPT, enabled the barriers and facilitators of putting the recommended elements within the guidance into practice, to be recognised and clarified.

10.3.3 Process evaluation

To illumine the process of implementation NPT was used to:

- Analyse findings from comparing data with a hypothesised logic model
- Identify and explain active ingredients
- Identify and explain mechanisms of change and impact
- Indicate feasibility
- Indicate fidelity
- Indicate level of normalisation.

This is the first time that NPT has been integrated with a logic model during analysis. This allowed me to answer the research questions relating to feasibility and fidelity of the implementation, by making explicit the active ingredients and mechanisms by which normalisation occurred. The method allowed me to drill down into the practical detail of what is feasible and what requires modification during implementation. It also indicated the facilitators and barriers to normalisation, and therefore sustainability and transferability.

10.3.4 Clinical situations

Considerable detail at an individual and organisational level was evidenced when I used NPT to demonstrate how to apply NICE PH Guidance (2010) in clinical situations in ways that promote normalisation.

More specifically, I used NPT to explain the requirements of organisations and individuals when supporting pregnant women to stop smoking through maternity and stop smoking services. These detailed findings add to the knowledge-base.

10.3.5 Conclusion

In this thesis I have explored the potential to close the theory-practice gap by using NPT. I have accomplished this through understanding the process of normalisation more fully and considering fidelity, feasibility and context for an example intervention. The new knowledge that this study contributes is to reduce this gap using novel methods, in a new environment and in a different topic area. This is achieved through combining logic modelling and NPT into the analytical method to reveal new knowledge about normalisation in an unpublished topic area. Recommendations arising from this new knowledge follow in the next section.

10.4 Recommendations

My main finding from this research study is that awareness and understanding of the processes involved in normalising any practice addition or change need to be raised amongst those designing public health interventions of any level of complexity, but particularly where complexity exists within the intervention and the context. In this way, theory can more readily be translated into practice, reducing the gap between them. NPT, or similar, should be routinely incorporated into the study protocol when implementing trial-based interventions into complex, public health systems.

My first, subsidiary finding is that NPT can be used creatively and adapted to specific study requirements, including being employed at multiple points in the evaluation cycle and used with logic modelling. NPT should be used flexibly and widely to strengthen research findings relating to complex, public health interventions.

My second, subsidiary finding is that there were several issues encountered when applying NPT that require attention. These include: terminology, boundaries of concepts, balancing linearity with iteration and lack of standardisation with flexibility, and the impact of context.

Further work is required to address these issues; bearing in mind that some issues relating to context may in part have been due to a lack of data.

10.5 Implications for future research

10.5.1 Future research on NPT

Findings from this research demonstrate the benefits of recognising the equality of qualitative approaches, like NPT, when used alongside experimental designs. Researchers could become more open to integrating experimental and non-experimental methodologies and methods when conducting evaluation in healthcare. To do this they will require training in combining research methods. 'Researchers' includes quantitative and qualitative data collectors and data analysers, knowledge translators and co-creators.

There are several areas where the literature is silent in terms of worked examples of NPT. Although NPT is suitable to be applied before, during and after the implementation process; it is usually only applied at one time point in each study. Comparing stages of normalisation at different time points during implementation would add to researchers' understanding of the process; active ingredients, mechanisms, barriers and facilitators could be clarified more readily.

NPT may be suitable for use in large-scale studies; however so far, the majority of published papers report its use in small studies. Potentially, using NPT on a larger scale would show researchers, if and how, they can employ the theory to clarify and compare normalisation processes, across multiple and/or varied sites and settings. Applying NPT more widely, and to more systems, settings and populations, would build up an increasingly substantial evidence-base to investigate the utility of the theory and its limitations.

There is also very little literature concerning identification of the process of implementation. This thesis has shown that lack of knowledge concerning the details of mechanisms and active ingredients, what they are, how, why and when they work, leads to disappointing outcomes. Clarifying exactly what is happening during normalisation is vital in terms of the theory-practice gap. Combining logic modelling and NPT has been found to be useful in this clarification process. Therefore, I recommend that more research is conducted using NPT to frame the process evaluation, using ToC, and combining NPT with a logic model for analysis.

Environment and context are known from the literature to be foundational and overarching issues that impact on implementation; however, NPT has not been used widely to consider them in depth. Using NPT offered me some opportunity to consider them and the findings support their centrality. I suggest NPT is suitable to consider them more closely. Researchers could use NPT specifically to explore the theory-practice gap at every contextual level i.e. international, national, regional, local; system, organisational, team, individual. A study would need to be designed with this focus in mind; probably collecting data from multiple source types.

Once researchers are confident that the detailed process can be clarified using a combination of NPT and logic modelling, it becomes possible to explore how, when and in what context, intervention components (ingredients) are critical or optional. The benefit of understanding the process in this depth is that its feasibility in a given context can be assessed. As can the need for absolute fidelity or the opportunity for adaptation, without losing effectiveness.

Future studies that use NPT to focus on feasibility and fidelity would be in a good position to judge an intervention's sustainability in a given context. Understanding the process of normalisation of an intervention and adapting it so that any gains are maintained, will provide the knowledge required to promote sustainability and, in time, transferability. Therefore, I recommend further work using NPT to focus on sustainability and transferability of complex public health interventions.

Findings from this study revealed that research is required into how NPT can be used more comprehensively to analyse several important issues that impact on implementation. These issues are:

- Leadership (senior/middle managers, opinion-leaders, champion)
- Environment (context at every level and aspect)
- Culture (organisation, group).

These ingredients are characterised by being fundamentally important to every implementation process, at every time point, and yet are not specifically captured by any of the NPT core concepts. Ways to use NPT to ensure that they are not missed would be beneficial for future studies.

The interplay of multiple levels of context on the intended outcomes was not fully comprehended when using NPT in this study. How NPT can contribute to understanding the interplay of organisational/frontline-clinical contexts and the impact on group/individual behaviour change requires further enquiry. An example of this would be: the impact of the healthcare system, Trust directives, policies, organisational systems, resourcing decisions etc. upon everyday practice for midwifery teams and individual team members, which in turn impact upon the service available or delivered to patients.

There were several internal challenges to NPT identified in this thesis. To date, the majority of the theory development and many of the applications have been undertaken by a small group of researchers. Although the number of published studies by other teams is increasing, these challenges still need to be addressed. To strengthen the theory, more work by research teams, some of them independent of the theory developers, is recommended into the following five areas:

i) The theory terms were unfamiliar, and work continues to be published that defines them differently. The aim of future research would be to define them more clearly and in accessible language.
ii) NPT is designed to make transparent the process by which new interventions (or changes) become embedded into routine practice. The theory did not fully explain the process in the study example, in part due to the study design. Study designs are required that use NPT to fully comprehend the normalisation process.
iii) Some core concepts have been reported more than others. Further work is required to determine if all the core concepts are of equal value in normalisation.
iv) There is a challenge when applying NPT in both linear and iterative ways in the same study. This may be reflecting what is happening in the process due to complexity; however, a clear method for applying the theory and reporting the findings is required.
v) There were lacunae in the dataset where more information was required about contexts. Work is required on methods to address and integrate all contextual levels within an NPT framework.

There are several ways that researchers could try to overcome the limitations of NPT identified in the thesis e.g.

- By retaining the ‘larger’ core concepts only and allowing researchers to put their data into their own specific sub-groups, rather than ones designated by theory authors
- By researchers devising their own, systematic solutions to defining terms and overlap of constructs

- By researchers applying additional methods during analysis, where data remains outside the coding frame/NPT concepts.

The evidence base would benefit from reporting on the results from applying these solutions.

This thesis extends the use of NPT by combining it with a logic model. This suggests the possibility of combining NPT and other theories, approaches and analytical methods. There may be potential for combining NPT and logic modelling with work from the fields of:

- Realist evaluation
- Knowledge translation
- Organisational culture
- Change management.

Realist evaluation and NPT share an ontology and epistemology, giving rise to the idea that they may work well together. One study has been designed using them both, combining NPT as a theoretical framework with realist evaluation analytical methods (Lewis *et al.*, 2018). More studies would be required to thoroughly check the feasibility of this study design.

The knowledge translation field allies closely with reducing the theory-practice gap. It is through creating ways to move research knowledge, from its originators to the decision-makers and users of the findings, that the information can be applied to produce the intended outcomes effectively. This research has shown how NPT has a role to play in this translation process. Further research is needed to explore and develop its aptitude for use in knowledge translation.

Organisational culture is known to be a key factor in determining response to change (Jacobs *et al.*, 2013; André and Sjøvold, 2017). Culture is a part of the context of any implementation. NPT was found to acknowledge culture without considering it in detail; neither was it intended to do so. Research that uses NPT as a framework to look into culture more deeply would cover new ground.

Change management is another field which has grown over recent decades. Again, NPT brushes up against it, acknowledging its importance, without fully embracing it. Combining NPT with evidence from the change management literature is likely to reveal new facets of the theory and implementation process, with potential to further reduce the theory-practice gap.

‘Elasticity’ and ‘plasticity’ are newly-minted terms (May, 2013a; 2013b; May, Johnson and Finch, 2016). They are designed to expand on the core concepts of NPT to provide a ‘more comprehensive explanation’ of the implementation process (May, Johnson and Finch, 2016, p1 of 14). Research using these terms requires application to new studies to determine to what extent they overcome the issues identified when applying NPT in this thesis.

10.5.2 Promoting knowledge translation

This research has found that the theory-practice gap exists in part because certain types of knowledge are preferred over others. Research questions that ask about the process are required to redress this balance. Study designs that incorporate creation of all appropriate knowledge types to answer these process questions should not be overlooked during implementation planning. I recommend that findings from using NPT, or similar, when implementing complex, public health interventions be incorporated into trial-based guidance, such as NICE PH Guidance (2010), to narrow the theory-practice gap.

Knowledge translation is required for successful sustainability and transferability of interventions. Research into routes to translate knowledge to stakeholders about normalisation of an intervention require exploring both at the primary site, and at the target site on scaling up and out.

10.5.3 Future research on babyClear©

The dataset used in the thesis was collected during the first implementation of the intervention across a region. The evaluation study design advanced knowledge in several ways, including measures of effectiveness and cost-effectiveness and understanding of the process (Bell *et al.*, 2018; Jones *et al.*, 2019). As a result of our evaluation, babyClear© is being cited in national reports as an example of an intervention that can improve smoking quit rates in pregnancy (DH, 2017; Davies, 2018). It is also gradually being introduced into other areas (Ireland, 2019).

The thesis itself took the understanding of the process of implementing babyClear© further. Using NPT with a logic model allowed the processes i.e. mechanisms and active ingredients, behind the numbers, to be more fully recognised. This offered the opportunity to hypothesise the most likely contexts for sustainability and transferability and inform the adaptation of the intervention to different settings. There is now an opportunity to use the findings from the thesis to improve the implementation of the intervention in several ways.

In future research into babyClear© the gaps in this dataset would need to be avoided. Any future dataset would benefit from obtaining contextual data from other sources (documentary) and levels (strategic, commissioner) so that the analysis could be more complete.

The study design kept the effectiveness and process evaluation work packages separate, although they were reported together at the end. There was no system for the findings from one to inform the other during the project e.g. for the effectiveness findings to provoke different interview questions or for feedback from the qualitative data to change practice and be able to link it with increased effectiveness. Full integration of experimental and observational designs is not commonplace. Study designs that are able to work towards further integration are still required; to take a step towards closer integration I recommend the recording and analysing of existing and changing contexts in any future study and retrospectively linking them with changes in effectiveness outcomes over time, including time-points pre, during and post-implementation.

In a similar fashion, there was no logic model extant at the commencement of the implementation. The retrospective logic model in the thesis represents the programme theory at the start point. I recommend that an updated logic model is created, that incorporates the findings from this thesis. This could be embellished further by other studies researching the implementation of babyClear©.

With an updated logic model and a dataset that has more contextual data, a new opportunity is created to assess sustainability, intended outcomes and transferability of babyClear© using NPT.

10.5.4 Implications for policy and practice

BabyClear© is being cited in national reports as being effective in reducing SiP (DH, 2017; Davies, 2018). Consequently, it is being adopted into policy documents, as the intervention of choice in some areas (Ireland, 2019). However, my findings suggest that without the detailed, transferable knowledge about how to implement and adapt it in context, expected outcomes are unlikely to be realised consistently. This knowledge can be provided by using NPT, or similar, and there is a risk that babyClear© will underperform unless this is rectified. There is an urgent need for dissemination of the mechanisms and ingredients required for optimal performance.

Findings reported in this thesis confirm the importance of recognising the requirements of the normalisation process at every level i.e. in the healthcare system, organisation, as well as on the frontline (Jones *et al.*, 2019). Once the details are known, it is incumbent on those with power and authority, such as senior leaders, to enable facilitating factors and remove barriers to normalisation, so that change can happen more successfully. Facilitators and barriers can include organisational context and culture, such as obstructive systems or resource decisions, as well as logistical issues.

Normalisation can be blocked at any point, including at the frontline. If the core principles within NPT are ignored e.g. the intervention does not make sense to staff, staff have not agreed to the idea, they cannot see how it can be implemented; it is unlikely to become embedded easily, if at all. Therefore, it is fundamental that there is greater understanding of the normalisation process by champions, team leaders and practitioners. This would enhance the implementation process by heightening awareness of the barriers and facilitators to routinising practice changes and support actions to promote normalisation.

REFERENCES

Aarons, G.A., *et al.* (2014) 'Mixed-method study of a conceptual model of evidence-based intervention sustainment across multiple public-sector service settings', *Implementation Science,* 9(183).

Aarts, J.W.M., *et al.* (2015) 'Title: Lessons learned from the implementation of an online infertility community into an IVF clinic's daily practice', *Human Fertility,* 18(4), pp. 238-247.

Action for Smoking and Health (2016) *Briefing: Electronic cigarettes 2*. Available at: http://ash.org.uk/stopping-smoking/ash-briefing-on-electronic-cigarettes-2/ (Accessed: 7th February 2019).

Action on Smoking and Health (2009) *Briefing: Electronic cigarettes*. Available at: http://casaa.org/wp-content/uploads/ASH_715-October-2009.pdf (Accessed: 16th May 2019).

Action on Smoking and Health (N.d.) *Home*. Available at: http://ash.org.uk/home/ (Accessed: 26th March 2019).

ActKnowledge (2013) *Center for Theory of Change*. Available at: http://www.theoryofchange.org/ (Accessed: 10th April 2019).

ActKnowledge (2019) *What is Theory of Change? - Background*. Available at: https://www.theoryofchange.org/what-is-theory-of-change/toc-background/toc-origins/ (Accessed: 16th May 2019).

Air Quality News (2013) *No Smoking Day campaign marks 30 years*. Available at: https://www.airqualitynews.com/2013/03/13/no-smoking-day-campaign-marks-30-years/ (Accessed: 18th May 2019).

Akker (1996) *PRINCE 2: Project Management*. Holland: Lagant.

Albrecht, S., *et al.* (2011) 'The SUCCESS Program for smoking cessation for pregnant women', *Journal of the Association of Women's Health, Obstetric and Neonatal Nurses,* 40(5), pp. 520-531.

Alharbi, T.S., *et al.* (2014) 'Implementation of person-centred care: management perspective', *Journal of Hospital Administration,* 3(3), pp. 107-120.

Alverbratt, C., *et al.* (2014) 'The process of implementing a new working method-a project towards change in a Swedish psychiatric clinic', *Journal of Hospital Administration,* 3(6), pp. 174-189.

André, B. and Sjøvold, E. (2017) 'What characterizes the work culture at a hospital unit that successfully implements change – a correlation study', *BMC Health Services Research,* 17(486).

Anku, P.J., *et al.* (2018) 'Integration of tuberculosis and HIV services: Exploring the perspectives of co-infected patients in Ghana', *Global Public Health,* 13(9), pp. 1192-1203.

Annandale, E. (1998) *The sociology of health medicine: a critical introduction.* Cambridge: Polity Press.

Anonymous (2005) 'Program: Smoke Free Mothers and Babies', *Health Education & Behavior,* 32(1), pp. 6-9.

Atkins, L.*, et al.* (2017) 'A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems', *Implementation Science,* 12(77).

Atkins, S.*, et al.* (2011) 'Provider experiences of the implementation of a new tuberculosis treatment programme: A qualitative study using the normalisation process model', *BMC Health Services Research,* 11(275).

Attride-Stirling, J. (2001) 'Thematic networks: an analytical tool for qualititative research', *Qualitative Research in Psychology,* 1(3), pp. 385-405.

Aveyard, P.*, et al.* (2005) 'Is advice to stop smoking from a midwife stressful for pregnant women who smoke? Data from a randomized controlled trial', *Preventive Medicine,* 40(5), pp. 575-582.

Awoonor-Williams, J.K. and Appiah-Denkyira, E. (2017) 'Bridging the intervention-implementation gap in primary health care delivery: the critical role of integrated implementation research', *BMC Health Services Research,* 17(Suppl 3), p. 772.

Ayadi, M.F.*, et al.* (2006) 'Costs of a smoking cessation counseling intervention for pregnant women: comparison of three settings', *Public Health Reports,* 121(2), pp. 120-126.

Baha, M.Y. and Le Faou, A.-L. (2009) 'Attitude towards cessation among French pregnant smokers: explaining the poor uptake of specialised support', *European Journal of Obstetrics & Gynecology and Reproductive Biology,* 147(1), pp. 46-51.

Bailey, B. (2015) 'Effectiveness of a Pregnancy Smoking Intervention: The Tennessee Intervention for Pregnant Smokers Program', *Health Education & Behavior,* 42(6), pp. 824-831.

Bamford, C.*, et al.* (2012) 'Implementing nutrition guidelines for older people in residential care homes: a qualitative study using Normalization Process Theory', *Implementation Science,* 7(106).

Bamford, C.*, et al.* (2014) 'Understanding the challenges to implementing case management for people with dementia in primary care in England: a qualitative study using Normalization Process Theory', *BMC Health Services Research,* 14(549).

Barker, D.J.P.*, et al.* (2002) 'Fetal origins of adult disease: strength of effects and biological basis', *International Journal of Epidemiology,* 31(6), pp. 1235-1239.

Batten, L. *et al.* (1999) 'Stage of change, low income and benefit status: a profile of women's smoking in early pregnancy'. *Health Education Journal*, 58(4), pp. 378-388.

Bauld, L., Angus, K. and de Andrade, M. (2014) *E-cigarette uptake and marketing.* London: University of Stirling.

Bauld, L.*, et al.* (2017) 'Barriers to and facilitators of smoking cessation in pregnancy and following childbirth: literature review and qualitative study', *Health Technology Assessment,* 21(36).

Bauld, L.*, et al.* (2012) 'Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy', *Addiction,* 107 (Suppl 2), pp. 53-60.

Baxter, S.*, et al.* (2010) 'Factors relating to the uptake of interventions for smoking cessation amongst pregnant women: a systematic review and qualitative synthesis', *Nicotine and Tobacco Research,* 12(7), pp. 685-694.

Bayliss, K.*, et al.* (2016) 'Implementing resources to support the diagnosis and management of chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) in primary care: a qualitative study', *BMC Family Practice,* 17(66).

Beck, A.T. (1967) '*Depression: Causes and Treatment*'. University of Pennsylvania.

Beck Institute (2016) *Beck Cognitive Behavior Therapy*. USA. Available at: https://beckinstitute.org/ (Accessed: 16th May 2019).

Beenstock, J.*, et al.* (2012) 'What helps and hinders midwives in engaging with pregnant women about stopping smoking? A cross-sectional survey of perceived implementation difficulties among midwives in the North East of England', *Implementation Science,* 7(36).

Bell, R.*, et al.* (2018) *Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation*. Tobacco Control. Available at: http://tobaccocontrol.bmj.com/content/early/2017/02/10/tobaccocontrol-2016-053476 (Accessed: 20th May 2019).

Benjamin, W. (1979) *One way street and other writings.* London: Sage.

Berger, P.L. and Luckmann, T. (1991) *The social construction of reality: a treatise in the sociology of knowledge.* London: Penguin.

Blakeman, T.*, et al.* (2012) 'Understanding the management of early-stage chronic kidney disease in primary care: a qualitative study', *British Journal of General Practice,* 62(597), pp. e233-e242.

Blamey, A. and Mackenzie, M. (2007) 'Theories of Change and Realistic Evaluation: peas in a pod or apples and oranges?', *Evaluation,* 13(4), pp. 439-455.

Blickem, C.*, et al.* (2014) 'Aligning everyday life priorities with people's self-management support networks: an exploration of the work and implementation of a needs-led telephone support system', *BMC Health Services Research,* 14(262).

Blumenthal-Barby, J.S. and Burroughs, H. (2012) 'Seeking better health care outcomes: the ethics of suing the "nudge"', *The American Journal of Bioethics,* 12(2), pp. 1-10.

BMC Implementation Science (2019) *Home*. Available at: https://implementationscience.biomedcentral.com/ (Accessed: 12th February 2019).

Boaz, A., Baeza, J. and Fraser, A. (2016) 'Does the ‘diffusion of innovations’ model enrich understanding of research use? Case studies of the implementation of thrombolysis services for stroke', *Journal of Health Services Research & Policy,* 21(4), pp. 229-234.

Bonell, C.*, et al.* (2012) 'Realist randomised controlled trials: A new approach to evaluating complex public health interventions', *Social Science & Medicine,* 75(12), p. 2299e2306.

Bonell, C.*, et al.* (2013) 'Methods don't make assumptions, researchers do: A response to Marchal et al', *Social Science & Medicine,* 94, pp. 81-82.

Bonell, C.*, et al.* (2018) 'Are randomised controlled trials positivist? Reviewing the social science and philosophy literature to assess positivist tendencies of trials of social interventions in public health and health services', *Trials,* 19(238).

Borland, T.*, et al.* (2013) 'Exploring the adequacy of smoking cessation support for pregnant and postpartum women', *BMC Public Health,* 13, p. 472.

Borman, B., Wilson, N. and Maling, C. (1999) 'Socio-demographic characteristics of New Zealand smokers: results from the 1996 census', *New Zealand Medical Journal,* 112 (1101), pp. 460-463.

Bouamrane, M.-M. and Mair, F.S. (2014a) 'Implementation of an integrated preoperative care pathway and regional electronic clinical portal for preoperative assessment', *BMC Medical Informatics and Decision Making,* 14(93).

Bouamrane, M.-M. and Mair, F.S. (2014b) 'A qualitative evaluation of general practitioners’ views on protocol-driven eReferral in Scotland', *BMC Medical Informatics and Decision Making,* 14(30).

Bouamrane, M.-M. and Mair, F.S. (2014c) 'A study of clinical and information management processes in the surgical pre-assessment clinic', *BMC Medical Informatics and Decision Making,* 14(22).

Bouamrane, M.-M., Osbourne, J. and Mair, F.S. '5th International ICST Conference on Pervasive Computing Technologies for Healthcare 2011'. *Pervasive Computing Technologies for Healthcare (Pervasive Health)*, Dublin, Ireland, 23-26 May. 300-307.

Boudon, R. (1991) 'What middle-range theories are', *Contemporary Sociology,* 20(4), pp. 519–522.

Boyd, K. and Sinclair, L. (2015) 'Smoking Cessation in Pregnancy Incentives Trial (CPIT): a phase II RCT with economic evaluation', *ASH Scotland Conference 2015*.

Brand, S.L.*, et al.* (2019) 'Building programme theory to develop more adaptable and scalable complex interventions: Realist formative process evaluation prior to full trial', *Evaluation,* 25(2), pp. 1–22.

Brannen, J. (2005) 'Mixing Methods: The Entry of Qualitative and Quantitative Approaches into the Research Process', *International Journal of Social Research Methodology,* 8(3), pp. 173-184.

Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology', *Qualitative Research Psychology,* 3, pp. 77-101.

Breuer, E.*, et al.* (2016) 'Using theory of change to design and evaluate public health interventions: a systematic review', *Implementation Science,* 11(63).

British Broadcasting Corporation (2011) *Misbehaving Mums-to-be*. London: BBC.

Britton, J. and Bogdanovica, I. (2014) *Electronic cigarettes: a report commissioned by Public Health England.* Nottingham: Public Health England.

Brooks, H.*, et al.* (2015) 'Re-inventing care planning in mental health: stakeholder accounts of the imagined implementation of a user/carer involved intervention', *BMC Health Services Research,* 15(490).

Brousselle, A. and Buregeya, J.-M. (2018) 'Theory-based evaluations: framing the existence of a new theory in evaluation and the rise of the 5th generation', *Evaluation,* 24(2), pp. 153-168.

Browne, S.*, et al.* (2014) 'Patient, carer and professional perspectives on barriers and facilitators to quality care in advanced heart failure', *PloS One,* 9(3), p. e93288.

Bryce, A.*, et al.* (2009) 'CATCH: development of a home-based midwifery intervention to support young pregnant smokers to quit', *Midwifery,* 25(5), pp. 473-482.

Bryk, A.R. (2016) 'Fidelity of implementation: Is it the right concept?', *Carnegie Commons Blog*, March 17th. Available at: https://www.carnegiefoundation.org/blog/fidelity-of-implementation-is-it-the-right-concept/ (Accessed: 10th April 2019).

Bryman, A. (2012) *Social research methods.* Oxford: Oxford University Press.

Bull, L. (2007) 'Smoking cessation intervention with pregnant women and new parents (part 2): A focus group study of health visitors and midwives working in the UK', *Journal of Neonatal Nursing,* 13(5), pp. 179-185.

Bullock, L.*, et al.* (2009) 'Baby BEEP: a randomized controlled trial of nurses' individualized social support for poor rural pregnant smokers', *Maternal & Child Health Journal,* 13, pp. 395-406.

Bunge, M. (2004) 'How does it work? The search for explanatory mechanisms', *Philosophy of the Social Sciences,* 34(2), pp. 182–210.

Cabinet Office (2019) *What Works Network*: Cabinet Office, England. Available at: https://www.gov.uk/guidance/what-works-network (Accessed: 12th February 2019).

Campbell, D. (2017) 'Test all pregnant women for smoking, say NHS chiefs', *The Guardian*, 26th February. Available at: https://www.theguardian.com/society/2017/feb/26/nhs-test-all-pregnant-women-for-smoking-nice-rcm (Accessed: 18th May 2019).

Campbell, E.*, et al.* (2006) 'A group randomised trial of two methods for disseminating a smoking cessation programme to public antenatal clinics: effects on patient outcomes', *Tobacco Control,* 15(2), pp. 97-102.

Campbell, N.C.*, et al.* (2007) 'Designing and evaluating complex interventions to improve health care', *British Medical Journal,* 334(3 March), pp. 455-459.

Carstensen, K., Brostrom Kousgaard, M. and Burau, V. (2019) 'Sustaining an intervention for physical health promotion in community mental health services: A multisite case study', *Health & Social Care In The Community,* 27(2), pp. 502-515.

Challenge Group (2018) *Review of the challenge 2018.* Available at: http://ash.org.uk/information-and-resources/reports-submissions/reports/smoking-in-pregnancy-challenge-group-review-of-the-challenge-2018/ (Accessed: 10th April 2019).

Chamberlain, C.*, et al.* (2013) *Psychosocial interventions for supporting women to stop smoking in pregnancy (Review)*: The Cochrane Collaboration. Available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001055.pub4/abstract (Accessed: 23rd May 2019).

Charmaz, K. (2012) *Constructing grounded theory: a practical guide through qualitative analysis.* London: Sage.

Chiang, P.P.*, et al.* (2015) 'Implementing a Q Cancer risk tool into general practice consultations: an exploratory study using simulated consultations with Australian general practitioners', *British Journal of Cancer,* 112, pp. S77-S83.

Clarke, D.J.*, et al.* (2013) 'Implementing a training intervention to support caregivers after stroke: a process evaluation examining the initiation and embedding of programme change', *Implementation Science,* 8(96).

Clarke, D.J.*, et al.* (2014) 'Introducing structured caregiver training in stroke care: findings from the TRACS process evaluation study', *BMJ Open,* 4(4), p. e004473.

Cluss, P.A., Levine, M.D. and Landsittel, D. (2011) 'The Pittsburgh STOP Program: disseminating an evidence-informed intervention for low-income pregnant smokers', *American Journal of Health Promotion,* 25(5), pp. S75-S81.

Cochrane (2016) *News: Cochrane announces new partnership with the Joanna Briggs Institute*. Available at: https://www.cochrane.org/news/cochrane-announces-new-partnership-joanna-briggs-institute (Accessed: 12th February 2019).

Coldwell, M. (2019) 'Reconsidering context: Six underlying features of context to improve learning from evaluation', *Evaluation,* 25(1).

Collins, N. (2013) 'Maternity wards closure crisis', *The Telegraph*, 15th June. Available at: http://www.telegraph.co.uk/news/health/news/10122702/Maternity-wards-closure-crisis.html (Accessed: 18th May 2019).

Conn, L.G.*, et al.* (2015) 'Successful implementation of an enhanced recovery after surgery programme for elective colorectal surgery: a process evaluation of champions' experiences', *Implementation Science,* 10(99).

Connelly, S. and Vanderhoven, D. (2018) 'The craft of evaluative practice: negotiating legitimate methodologies within complex interventions', *Evaluation,* 24(4), pp. 1-19.

Consumer Advocates for Smokefree Alternatives Association (CASAA) (2012-2019) *A historial timeline of electronic cigarettes*. Available at: http://casaa.org/historical-timeline-of-electronic-cigarettes/ (Accessed: 17th May 2019).

Cooper, S.*, et al.* (2017) 'Smoking and quit attempts during pregnancy and postpartum: a longitudinal UK cohort', *BMJ Open,* 7(11), p. e018746.

Coote, A., Allen, J. and Woodhead, D. (2004) *Finding out what works: understanding complex, community-based initiatives.* [Policy paper] London: King's Fund.

Craig, P. and Campbell, M. (2015) *Evaluability Assessment: a systematic approach to deciding whether and how to evaluate programmes and policies.* [Working Paper] University of Glasgow: What Works Scotland. Available at: http://whatworksscotland.ac.uk/new-working-paper-published-evaluability-assessment/ (Accessed: 10th April 2019).

Craig, P. *et al.* (2009) *Using natural experiments to evaluate population health interventions: guidance for producers and users of evidence*. UK Medical Research Council, Population Health Science Research Network.

Craig, P. *et al*. (2008) *Developing and evaluating complex interventions: new guidance*. London: UK Medical Research Council. (Accessed: 10th April 2019).

Craig, P.*, et al.* (2013) 'Developing and evaluating complex interventions: the new Medical Research Council guidance', *International Journal of Nursing Studies,* 50(5), pp. 585-592.

Craig, P.*, et al.* (2019) *Developing and Evaluating Complex Interventions: draft of updated guidance*. Available at: https://www.sphsu.gla.ac.uk/stakeholder-survey-2019/Full%20complex%20guidance%20draft%20for%20consultation%20v1.1%2026.03.19.pdf (Accessed: 2nd May 2019).

Crang, M. (2003) 'Telling materials', in Pryke, M., Rose, G. and Whatmore, S. (eds.) *Using social theory: thinking through research*. London: Sage.

Cresswell, J.W. and Poth, C.N. (2018) *Qualitative enquiry and research design.* 4th edn. London: Sage.

Crotty, M. (1998) *The foundations of social research: meaning and perspective in the research process.* London: Sage.

Crozier, S.*, et al.* (2009) 'Do women change their health behaviours in pregnancy? Findings from the Southampton Women's Survey', *Paediatric and Perinatal Epidemiology,* 23(5), pp. 446-453.

Davies, S. (2018) *Chief Medical Officer annual report 2018: better health within reach* London: DHSC. Available at: https://www.gov.uk/government/publications/chief-medical-officer-annual-report-2018-better-health-within-reach.

Denison Consulting (2018) *Organizational Culture Surveys: How aligned is your organizational culture? Don't guess – know*. Available at: https://www.denisonconsulting.com/culture-surveys/ (Accessed: 15th March 2019).

Department for Communities and Local Government (2015) *The English Indices of Deprivation 2015: statistical release*. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/465791/English_Indices_of_Deprivation_2015_-_Statistical_Release.pdf (Accessed: 20th March 2019).

Department for Health and Social Care (2015) *News story: Smoking in cars with children banned from today*. Available at: https://www.gov.uk/government/news/smoking-in-cars-with-children-banned-from-today (Accessed: 16th May 2019).

Department of Health (1998) *Smoking kills: a white paper on tobacco*. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/260754/4177.pdf (Accessed: 10th April 2019).

Department of Health (2006) *The Health Act, c. 88,*. London: HM Government. Available at: http://www.legislation.gov.uk/uksi/2006/2603/contents/made (Accessed: 16th May 2019).

Department of Health (2011a) *Healthy lives, healthy people: a tobacco control plan for England.* Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213757/dh_124960.pdf (Accessed: 10th April 2019).

Department of Health (2011b) *A simple guide to Payment by Results (PbR)*. London: DH. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213150/PbR-Simple-Guide-FINAL.pdf (Accessed: 17th May 2019).

Department of Health (2012) *Health and Social Care Act*. Available at: http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted (Accessed: 10th April 2019).

Department of Health (2017) *Towards a smokefree generation: a tobacco control plan for England*. Available at: https://www.gov.uk/government/publications/towards-a-smoke-free-generation-tobacco-control-plan-for-england (Accessed: 10th April 2019).

Department of Health and Social Care (2014) *Simple guide to the maternity services pathway payment system*. Available at: https://www.gov.uk/government/news/simple-guide-to-the-maternity-services-pathway-payment-system-published (Accessed: 17th May 2019).

Department of Health and Social Care (2018a) *Tobacco Control Delivery Plan 2017 - 2022*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/714365/tobacco-control-delivery-plan-2017-to-2022.pdf (Accessed: 26th March 2019).

Department of Health and Social Care (2018b) *Tobacco Control Plan: Delivery Plan 2017 - 2022*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/714365/tobacco-control-delivery-plan-2017-to-2022.pdf (Accessed: 20th May 2019).

DePoy, E. and Gitlin, L. (2005) *Introduction to research: understanding and applying multiple strategies.* 3rd edn. St. Louis: Elsevier Mosby.

Doll, R.*, et al.* (1994) 'Mortality in relation to smoking: 40 years' observations on male British doctors', *British Medical Journal,* 309(901).

Donnan, S. (2002) 'Ethics in public health', in Pencheon, D.*, et al.* (eds.) *Oxford Handbook of Public Health Practice*. Oxford: Oxford University Press.

Dooley, K. (1997) 'A complex adaptive systems model of organizational change', *Non-linear Dynamics Psychology & Life Sciences,* 1(1), pp. 69-97.

Drew, S.*, et al.* (2015) 'Implementation of secondary fracture prevention services after hip fracture: a qualitative study using extended Normalization Process Theory', *Implementation Science,* 10(1).

Eckley, B., Ruddick, A. and Walker, R. (2015) *Fullness of life together: reimagining Christian engagement in our communities*. Available at: http://www.livability.org.uk/fullness-of-life-together-report/ (Accessed: 10th April 2019).

Education Endowment Fund (2015) *Promoting Alternative Thinking Strategies*. Available at: https://educationendowmentfoundation.org.uk/projects-and-evaluation/projects/promoting-alternative-thinking-strategies/ (Accessed: 12th February 2019).

Ehrlich, C., Kendall, E. and John, W.S. (2013) 'How does care coordination provided by registered nurses ‘‘fit’’ within the organisational processes and professional relationships in the general practice context?', *Collegian,* 20(3), pp. 127-135.

El-Mohandes, A.A.*, et al.* (2011) 'Smoking cessation and relapse among pregnant African-American smokers in Washington, DC', *Maternal & Child Health Journal,* 15, pp. S96-105.

Elf, M.*, et al.* (2018) 'The Swedish version of the Normalization Process Theory Measure S-NoMAD: translation, adaptation, and pilot testing', *Implementation Science,* 13(146).

Elwyn, G.*, et al.* (2008) 'Arduous implementation: Does the Normalisation Process Model explain why it's so difficult to embed decision support technologies for patients in routine clinical practice', *Implementation Science,* 3(57).

Ershoff, D.H.*, et al.* (1999) 'The Kaiser Permanente Prenatal Smoking-Cessation Trial when more isn’t better, what is enough?', *American Journal of Preventive Medicine,* 17(3).

Escoffery, C.*, et al.* (2018) 'A systematic review of adaptations of evidence-based public health interventions globally', *Implementation Science,* 13(125).

Evaluation Support Scotland (2012-2019) *Home: Partnerships: Knowledge translation network*. Available at: http://www.evaluationsupportscotland.org.uk/our-work-partners/knowledge-translation/knowledge-translation-network/ (Accessed: 15th March 2019).

Evans, R., Scourfield, J. and Murphy, S. (2015) 'Pragmatic, formative process evaluations of complex interventions and why we need more of them', *Journal of Epidemiology & Community Health,* 69(10), pp. 925–926.

Everett-Murphy, K.*, et al.* (2011) 'Scolders, carers or friends: South African midwives' contrasting styles of communication when discussing smoking cessation with pregnant women', *Midwifery,* 27(4), pp. 517-524.

Evidence Centre (2011) *High Reliability Organisations: Research Scan.* London: The Health Foundation.

Fahy, S.J.*, et al.* (2014) 'Provision of smoking cessation support for pregnant women in England: results from an online survey of NHS stop smoking services for pregnant women', *BMC Health Services Research,* 14(107).

Fendall, L. (2018) Email Jones, S., 19th September.

Fendall, L.*, et al.* (2012) 'Integrating a clinical model of smoking cessation into antenatal care', *British Journal of Midwifery,* 20(4), pp. 236-243.

Finch, T. (2008) 'Teledermatology for chronic disease management: coherence and normalization', *Chronic Illness,* 4(2), pp. 127-134.

Finch, T.L.*, et al.* (2018) 'Improving the normalization of complex interventions: part 2 - validation of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT)', *BMC Medical Research Methodology,* 18(1), p. 135.

Finch, T.L.*, et al.* (2012) 'From theory to 'measurement' in complex interventions: methodological lessons from the development of an e-health normalisation instrument', *BMC Medical Research Methodology,* 12(69).

Finch, T.L., Mair, F.S. and May, C.R. (2007) 'Teledermatology in the U.K.: lessons in service innovation', *British Journal of Dermatology,* 156(3), pp. 521-527.

Finch, T.L.*, et al.* (2013) 'Improving the normalization of complex interventions: measure development based on normalization process theory (NoMAD): study protocol', *Implementation Science,* 8(43).

Flemming, K.*, et al.* (2013) 'Smoking in pregnancy: a systematic review of qualitative research of women who commence pregnancy as smokers', *Journal of Advanced Nursing,* 69(5), pp. 1023-1036.

Flemming, K.*, et al.* (2015) 'Qualitative systematic review: barriers and facilitators to smoking cessation experienced by women in pregnancy and following childbirth', *Journal of Advanced Nursing,* 71(6), pp. 1210-1226.

Fletcher, A.*, et al.* (2016) 'Realist complex intervention science: applying realist principles across all phases of the Medical Research Council framework for developing and evaluating complex interventions', *Evaluation,* 22(3), pp. 286-303.

Forster, D.A.*, et al.* (2011) 'Exploring implementation and sustainability of models of care: can theory help?', *BMC Public Health,* 11(S8).

Foss, C.*, et al.* (2005) 'The challenges associated with implementing new practice: Normalisation Process Theory can be used to assess the prerequisites for ensuring that a new intervention becomes established practice', *Scandinavian Journal of Public Health,* 33(1), pp. 4–10.

Franx, G.*, et al.* (2012) 'Implementing a stepped-care approach in primary care: results of a qualitative study', *Implementation Science,* 7(8).

Fresh NE (2014) *Don't be the 1* [Campaign]. Available at: http://www.freshne.com/what-we-do/our-campaigns/dont-be-the-1/activity (Accessed: 17th May 2019).

Furler, J.*, et al.* (2011) 'Insulin in general practice: Barriers and enablers for timely initiation', *Australian Family Physician,* 40 (6), pp. 617-621.

Fuse - the Centre for Translational Research in Public Health (No date) *Translational research*. Available at: http://www.fuse.ac.uk/research/translationalresearch/ (Accessed: 15th March 2019).

Gabbay, M.B.*, et al.* (2017) 'Debt counselling for depression in primary care: an adaptive randomised controlled pilot trial (DeCoDer study)', *Health Technology Assessment,* 21(35).

Gadomski, A.*, et al.* (2011) 'Effectiveness of a combined prenatal and postpartum smoking cessation program', *Maternal & Child Health Journal,* 15(2), pp. 188-197.

Gage, J.D., Everett, K.D. and Bullock, L. (2007) 'A review of research literature addressing male partners and smoking during pregnancy', *Journal of Obstetric, Gynecologic & Neonatal Nursing,* 36(6), pp. 574-580.

Gallacher, K.*, et al.* (2010) 'Assessing treatment burden in chronic heart failure patients', *Heart,* 96(S1).

Gallacher, K.*, et al.* (2011) 'Understanding patients' experiences of treatment burden in chronic heart failure using Normalization Process Theory', *Annals of family medicine,* 9(3), pp. 235-243.

Gallacher, K.I.*, et al.* (2018) 'A conceptual model of treatment burden and patient capacity in stroke', *BMC Family Practice,* 19(1).

Galloway, M. (2012) 'Cut it out! Smoking and pregnancy', *The Practising Midwife,* 15(5), pp. 35-38.

Gask, L.*, et al.* (2010) 'What work has to be done to implement collaborative care for depression? Process evaluation of a trial utilizing the Normalization Process Model', *Implementation Science,* 5(15).

Gask, L.*, et al.* (2008) 'Beyond the limits of clinical governance? The case of mental health in English primary care', *BMC Health Services Research,* 8(63).

Gellatly, J.*, et al.* (2018) 'A qualitative study of professional stakeholders' perceptions about the implementation of a stepped care pain platform for people experiencing chronic widespread pain', *BMC Family Practice,* 19(151).

Gibbs, G. (1988) *Learning by doing: a guide to teaching and learning methods.* Oxford: Further Education Unit, Oxford Polytechnic.

Giddens, A. (1984) *The constitution of society.* Cambridge: Polity.

Gifford, W.A.*, et al.* (2014) 'Managerial leadership for research use in nursing and allied health care professions: a narrative synthesis protocol', *Systematic Reviews,* 3(1), p. 57.

Godden, D., John and King, G. (2011) 'Rational development of telehealth to support primary care respiratory medicine: patient distribution and organisational factors', *Primary Care Respiratory Journal,* 20(4), pp. 415-420.

Godfrey, M.*, et al.* (2013) 'Developing and implementing an integrated delirium prevention system of care: a theory driven, participatory research study', *BMC Health Services Research,* 13(341).

Goldthorpe, J.*, et al.* (2018) 'Exploring implementation of an electronic referral management system and enhanced primary care service for oral surgery: perspectives of patients, providers and practitioners', *BMC Health Services Research,* 18(646).

Graham, H.*, et al.* (2014) 'Cutting down: insights from qualitative studies of smoking in pregnancy', *Health & Social Care In The Community,* 22(3), pp. 259-267.

Grant, A., Dreischulte, T. and Guthrie, B. (2017) 'Process evaluation of the data-driven quality improvement in primary care (DQIP) trial: active and less active ingredients of a multi-component complex intervention to reduce high-risk primary care prescribing', *Implementation Science,* 12(4).

Grant, A.*, et al.* (2013) 'Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting', *Trials,* 14(15).

Grant, A.M., Guthrie, B. and Dreischulte, T. (2014) 'Developing a complex intervention to improve prescribing safety in primary care: mixed methods feasibility and optimisation pilot study', *BMJ Open,* 4(1), p. e004153.

Grant, R.L. and Hood, R. (2017) 'Complex systems, explanation and policy: implications of the crisis of replication for public health research', *Critical Public Health,* 27(5), pp. 525-532.

Great Britain (1998) *Data Protection Act*. London: The Stationery Office. Available at: https://www.gov.uk/data-protection/the-data-protection-act.

Green, T.*, et al.* (2015) 'Exploring GPs' experiences of using diagnostic tools for cancer: a qualitative study in primary care', *Family Practice,* 32(1), pp. 101-105.

Greenhalgh, T.*, et al.* (2009) 'How do you modernize a health service? A realist evaluation of wholescale transformation in London', *Milbank Quarterly,* 87(2), pp. 391-416.

Greenhalgh, T. and Papoutsi, C. (2018) 'Studying complexity in health services research: desperately seeking an overdue paradigm shift', *BMC Medicine,* 16(95).

Greenhalgh, T.*, et al.* (2004) 'Diffusion of innovations in service organizations: systematic review and recommendations', *Milbank Quarterly,* 82(4), pp. 581-629.

Gunn, J.M.*, et al.* (2010) 'Embedding effective depression care: using theory for primary care organisational and systems change', *Implementation Science,* 5(62).

Hall, A.*, et al.* (2016) 'Implementing a video-based intervention to empower staff members in an autism care organization: a qualitative study', *BMC Health Services Research,* 16(608).

Hannigan, A.*, et al.* (2018) 'Ethnic minority health in Ireland - Co-creating knowledge (EMH-IC): a participatory health research protocol', *BMJ Open,* 8(10), pp. e026335-e026335.

Harvey, G., Jas, P. and Walshe, K. (2015) 'Analysing organisational context: case studies on the contribution of absorptive capacity theory to understanding inter-organisational variation in performance improvement', *BMJ Quality & Safety,* 24(1), pp. 48-55.

Haslam, C. and Lawrence, W. (2004) 'Health-related behavior and beliefs of pregnant smokers', *Health Psychology,* 23(5), pp. 486-491.

Hawe, P., Shiell, A. and Riley, T. (2004) 'Complex interventions: how "out of control" can a randomised trial be?', *British Medical Journal,* 328, pp. 1561-1563.

Health News (2013) 'Sunderland mums among worst in the country for smoking in pregnancy', *Sunderland Echo*, December 19th.

Henderson, E.J. and Rubin, G.P. (2013) 'The utility of an online diagnostic decision support system (Isabel) in general practice: a process evaluation', *Journal of the Royal Society of Medicine short reports,* 4(5), p. 31.

Hennrikus, D.*, et al.* (2010) 'Increasing support for smoking cessation during pregnancy and postpartum: results of a randomized controlled pilot study', *Preventive Medicine,* 50(3), pp. 134-137.

Herber, O.R.*, et al.* (2018) 'Enhancing self-care adherence in patients with heart failure: a study protocol for developing a theory-based behaviour change intervention using the COM-B behaviour model (ACHIEVE study)', *BMJ Open,* 8(9), p. e025907.

Higgins, S.T.*, et al.* (2006) 'Smoking status in the initial weeks of quitting as a predictor of smoking-cessation outcomes in pregnant women', *Drug and Alcohol Dependence,* 85(2), pp. 138-141.

Higman, W.*, et al.* (2015) 'Assessing clinicians' knowledge and confidence to perform kangaroo care and positive touch in a tertiary neonatal unit in England using the Neonatal Unit Clinician Assessment Tool (NUCAT)', *Journal of Neonatal Nursing,* 21(2), pp. 72-82.

Hoberg, A.A.*, et al.* (2013) 'Feasibility evaluation of an interpersonal and social rhythm therapy group delivery model', *Archives of psychiatric nursing,* 27(6), pp. 271-277.

Hoddinott, P., Britten, J. and Pill, R. (2010) 'Why do interventions work in some places and not others: a breast-feeding support group trial', *Social Science & Medicine,* 70(5), pp. 769–778.

Hoek, J.*, et al.* (2012) 'Tobacco branding, plain packaging, pictorial warnings, and symbolic consumption', *Qualitative Health Research,* 22(5), pp. 630–639.

Hoek, J.*, et al.* (2014) 'A qualitative analysis of messages to promote smoking cessation among pregnant women', *BMJ Open,* 4(11), p. e006716.

Hoek, J. and Jones, S.C. (2011) 'Regulation, public health and social marketing: a behaviour change trinity', *Journal of Social Marketing,* 1(1), pp. 32-44.

Holtrop, J.S.*, et al.* (2016) 'Effect of care management program structure on implementation: a normalization process theory analysis', *BMC Health Services Research,* 16(386).

Hooker, L.*, et al.* (2015) 'Applying Normalization Process Theory to understand implementation of a family violence screening and care model in maternal and child health nursing practice: a mixed method process evaluation of a randomised controlled trial', *Implementation Science,* 10(39).

Iles, V. and Cranfield, S. (2005) *Really managing healthcare.* 2nd edn. Maidenhead: Open University Press.

Ireland, B. (2019) Email Jones, S., 9th February

ITV (Tyne Tees) (2013) *Protect unborn babies from smoking*. News [Television]. Available at: https://www.itv.com/news/tyne-tees/story/2013-12-19/health-programme-to-protect-unborn-babies-from-smoking/ (Accessed: 17th May 2019).

Jaakkola, N., Zahlsen, K. and Jaakkola, J.J.K. (2001) 'Effects of a population-based smoking cessation programme on smoking in pregnancy', *European Journal of Public Health,* 11(4), pp. 446-449.

Jacobs, R.*, et al.* (2013) 'The relationship between organizational culture and performance in acute hospitals', *Social Science & Medicine,* 76, pp. 115-125.

Jagosh, J.*, et al.* (2015) 'A realist evaluation of community-based participatory research: partnership synergy, trust building and related ripple effects', *BMC Public Health,* 15(1), p. 725.

James, D., M. (2011) 'The applicability of normalisation process theory to speech and language therapy: a review of qualitative research on a speech and language intervention', *Implementation Science,* 6(95).

Joanna Briggs Institute (2018) *About us*. Australia: Joanna Briggs Institute. Available at: http://joannabriggs.org/about.html (Accessed: 12th February 2019).

Johnson, R.B. and Onwuegbuzie, A.J. (2004) 'Mixed methods research: a research paradigm whose time has come', *Educational Researcher,* 33(7), pp. 14-26.

Jones, C.H.*, et al.* (2016) 'Embedding new technologies in practice–a normalization process theory study of point of care testing', *BMC Health Services Research,* 16(591).

Jones, M.*, et al.* (2018) 'A dynamic modifiable model for estimating cost-effectiveness of smoking cessation interventions in pregnancy: application to an RCT of self-help delivered by text message', *Addiction,* 114(2), pp. 353-365.

Jones, S.*, et al.* (2019) 'What helped and hindered implementation of an intervention package to reduce smoking in pregnancy: process evaluation guided by normalization process theory', *BMC Health Services Research,* 19(1), p. 297.

Joseph, J.G.*, et al.* (2009) 'Reducing psychosocial and behavioral pregnancy risk factors: results of a randomized clinical trial among high-risk pregnant African American women', *American Journal of Public Health,* 99(6), pp. 1053-1061.

Kelley, K., Bond, R. and Abraham, C. (2001) 'Effective approaches to persuading pregnant women to quit smoking: A meta-analysis of intervention evaluation studies', *British Journal of Health Psychology,* 6(3), pp. 207-228.

Kelly, E. and Lee, T. (2017) *More complex births puts strain on maternity services - which struggle more later in the week*: Institute for Fiscal Studies. Available at: https://www.ifs.org.uk/publications/9716 (Accessed: 1st June 2019).

Kempen, T.G.H.*, et al.* (2018) *A case study of the implementation and sustainability of medication reviews in older patients by clinical pharmacists*. Research in Social & Administrative Pharmacy. Available at: https://www.ncbi.nlm.nih.gov/pubmed/30606682 (Accessed: 1st June 2019).

Kennedy, A. *et al*. (2010) 'Delivering the WISE (Whole Systems Informing Self-Management Engagement) training package in primary care: learning from formative evaluation', *Implementation Science,* 5(7).

Kennedy, A.*, et al.* (2014) 'Implementing, embedding and integrating self-management support tools for people with long-term conditions in primary care nursing: a qualitative study', *International Journal of Nursing Studies,* 51(8), pp. 1103-1113.

Kitson, A.*, et al.* (2017) 'Using complexity and network concepts to inform healthcare knowledge translation', *International Journal of Health Policy and Management,* 7(3), pp. 1-13.

Koshy, P.*, et al.* (2010) 'Smoking cessation during pregnancy: the influence of partners, family and friends on quitters and non-quitters', *Health and Social Care in the Community,* 18(5), pp. 500-510.

Kreindler, S.A. (2018) 'Advancing the evaluation of integrated knowledge translation', *Health Research Policy and Systems,* 16(104).

Krueger, R.A. and Casey, M.A. (2015) *Focus groups: a practical guide for applied research.* 5th edn. Los Angeles, CA: Sage.

Kwasnicka, D.*, et al.* (2016) 'Theoretical explanations for maintenance of behaviour change: a systematic review of behaviour theories', *Health Psychology Review,* 10(3), pp. 277-296.

Lagan, B.M. and Casson, K. (2010) 'Support needs of women who continue to smoke in pregnancy', *British Journal of Midwifery,* 18(4), pp. 229-235.

Lamont, T.*, et al.* (2016) 'New approaches to evaluating complex health and care systems', *British Medical Journal,* 352(i154).

Lando, H.A.*, et al.* (2001) 'Promoting smoking abstinence in pregnant and postpartum patients: a comparison of two approaches', *American Journal of Managed Care,* 7(7), pp. 685-693.

Lane, P.J., Koka, B.R. and Pathak, S. (2006) 'The reification of absorptive capacity: a critical review and rejuvenation of the construct', *Academy of Management Review,* 31(4), pp. 833–863.

Latour, B. (2005) *Reassembling the social: an introduction to Actor-Network Theory.* Oxford: Oxford University Press.

Lawrence, T.*, et al.* (2003) 'A cluster randomised controlled trial of smoking cessation in pregnant women comparing interventions based on the transtheoretical (stages of change) model to standard care', *Tobacco Control,* 12(2), pp. 168-177.

Lawrence, W. and Haslam, C. (2007) 'Smoking during pregnancy where next for stage-based interventions?', *Journal of Health Psychology,* 12(1), pp. 159-169.

Lewis, A.*, et al.* (2018) 'Can oral healthcare for older people be embedded into routine community aged care practice? A realist evaluation using Normalisation Process Theory', *International Journal of Nursing Studies,* 94, pp. 32-41.

Lewis, L.*, et al.* (2016) 'Psychosocial characteristics and smoking behaviour in young Western Australian pregnant women at their first hospital appointment for pregnancy care', *Public Health,* August (137), pp. 192-195.

Lincoln, Y.S. and Guba, E. (1985) *Naturalistic inquiry.* Newbury Park, CA: Sage.

Lindson-Hawley, N.*, et al.* (2013) 'The importance of practitioner smoking status: a survey of NHS Stop Smoking Service practitioners', *Patient Education and Counseling,* 93(1), pp. 139-145.

Lindson-Hawley, N.*, et al.* (2016) 'Does cigarette reduction while using nicotine replacement therapy prior to a quit attempt predict abstinence following quit date?', *Addiction,* 111(7), pp. 1275-1282.

Lorencatto, F.*, et al.* (2016) 'Assessing the quality of goal setting in behavioural support for smoking cessation and its association with outcomes', *Annals of Behavioral Medicine,* 50(2), pp. 310-318.

Lorencatto, F., West, R. and Michie, S. (2012) 'Specifying evidence-based behavior change techniques to aid smoking cessation in pregnancy', *Nicotine and Tobacco Research,* 14(9), pp. 1019-1026.

Lowry, C., Scammell, K. and Challenge Group (2013) *Smoking cessation in pregnancy: A call to action*. Available at: http://ash.org.uk/information-and-resources/reports-submissions/reports/smoking-cessation-in-pregnancy/ (Accessed: 10th April 2019).

Lumley, J.*, et al.* (2009) 'Interventions for promoting smoking cessation during pregnancy', *Cochrane Database of Systematic Reviews,* 3, p. CD001055.

Lumley, J.*, et al.* (2004) 'Interventions for promoting smoking cessation during pregnancy', *Cochrane Database of Systematic Reviews,* 4.

Lupton, D. (2012) ''Precious cargo': foetal subjects, risk and reproductive citizenship', *Critical Public Health,* 22(3), pp. 329-340.

Lupton, D. (2014) 'The pedagogy of disgust: the ethical, moral and political implications of using disgust in public health campaigns', *Critical Public Health,* 25(1), pp. 4-14.

Lynch, E.A.*, et al.* (2018) '"There is nothing so practical as a good theory": a pragmatic guide for selecting theoretical approaches for implementation projects', *BMC Health Services Research,* 18(857).

Ma, Y.*, et al.* (2005) 'Predictors of smoking cessation in pregnancy and maintenance postpartum in low-income women', *Maternal & Child Health Journal,* 9(4), pp. 393-402.

MacFarlane, A. and O'Reilly-de Brún, M. (2012) 'Using a theory-driven conceptual framework in qualitative health research', *Qualitative Health Research,* 22(5), pp. 607-618.

Maden, M.*, et al.* (2017) 'Use of programme theory to understand the differential effects of interventions across socio-economic groups in systematic reviews-a systematic methodology review', *Systematic Reviews,* 6(266).

Mair, F.*, et al.* (2008) 'Understanding factors that inhibit or promote the utilization of telecare in chronic lung disease', *Chronic Illness,* 4(2), pp. 110-117.

Mair, F.*, et al.* (2012) 'Factors that promote or inhibit the implementation of e-health systems: an explanatory systematic review', *Bulletin of the World Health Organization,* 90, pp. 357-364.

Mantzari, E., Vogt, F. and Marteau, T.M. (2012) 'The effectiveness of financial incentives for smoking cessation during pregnancy: is it from being paid or from the extra aid?', *BMC Pregnancy & Childbirth,* 12(24).

Marchal, B.*, et al.* (2012) 'Is realist evaluation keeping its promise? A review of published empirical studies in the field of health systems research', *Evaluation,* 18(2), pp. 192-212.

Marchal, B.*, et al.* (2013) 'Realist RCTs of complex interventions–an oxymoron', *Social Science & Medicine,* 94, pp. 124-128.

Marmot, M. (2015) 'The health gap: the challenge of an unequal world', *Lancet,* 386, pp. 2442–2444.

Marmot Review Team (2010) *Fair Society, Healthy Lives: Strategic Review of Health Inequalities in England post-2010.* London: University College London. Available at: http://www.instituteofhealthequity.org/projects/fair-society-healthy-lives-the-marmot-review.

Marshall, J.E. and Raynor, M.D. (2014) *Myles Textbook for Midwives.* 16th edn. Edinburgh: Churchill Livingstone.

Mauriello, L.*, et al.* (2011) 'Acceptability and feasibility of a multiple-behavior, computer-tailored intervention for underserved pregnant women', *Journal of Midwifery and Women's Health,* 56(1), pp. 75-80.

Maxson, P.J.*, et al.* (2012) 'Psychosocial differences between smokers and non-smokers during pregnancy', *Addictive Behaviors,* 37(2), pp. 153-159.

Maxwell, J.A. (2013) *Qualitative research design: an interactive approach.* London: Sage.

May, C. (2006) 'A rational model for assessing and evaluating complex interventions in health care', *BMC Health Services Research,* 6(86).

May, C. (2013a) 'Agency and implementation: Understanding the embedding of healthcare innovations in practice', *Social Science & Medicine,* 78, pp. 26-33.

May, C. (2013b) 'Towards a general theory of implementation', *Implementation Science,* 8(18).

May, C.*, et al.* (2003) 'Health technology assessment in its local contexts: studies of telehealthcare', *Social Science & Medicine,* 57(4), pp. 697-710.

May, C.*, et al.* (2007a) 'Understanding the implementation of complex interventions in health care: the NormalizationProcess Model', *BMC Health Services Research,* 7(148).

May, C.*, et al.* (2007b) 'Process evaluation for complex interventions in primary care: understanding trials using the Normalization Process Model', *BMC Family Practice,* 8(42).

May, C.*, et al.* (2009) 'Development of a theory of implementation and integration: Normalization Process Theory', *Implementation Science,* 4(29).

May, C.*, et al.* (2011a) 'Evaluating complex interventions and health technologies using normalization process theory: development of a simplified approach and web-enabled toolkit', *BMC Health Services Research,* 11(245).

May, C.*, et al.* (2011b) 'Integrating telecare for chronic disease management in the community: What needs to be done?', *BMC Health Services Research,* 11(131).

May, C.*, et al.* (2014) 'Rethinking the patient: using burden of treatment theory to understand the changing dynamics of illness', *BMC Health Services Research,* 14(281).

May, C.*, et al.* (2015) *Normalization Process Theory on-line users' manual, toolkit and NoMAD instrument*. Available at: http://www.normalizationprocess.org (Accessed: 12th March 2019).

May, C.*, et al.* (2018) 'Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review', *Implementation Science,* 13(80).

May, C. and Finch, T. (2009) 'Implementing, embedding, and integrating practices: an outline of normalization process theory', *Sociology,* 43(3), pp. 535-554.

May, C., Johnson, M. and Finch, T. (2016) 'Implementation, context and complexity', *Implementation Science,* 11(141).

McBride, C.M.*, et al.* (2004) 'Prenatal and postpartum smoking abstinence: a partner-assisted approach', *American Journal of Preventive Medicine,* 27(3), pp. 232-238.

McBride, C.M., Emmons, K.M. and Lipkus, I.M. (2003) 'Understanding the potential of teachable moments: the case of smoking cessation', *Health Education Research,* 18(2), pp. 156-170.

McCance, T. and McCormack, B. (2017) *Person-centred practice in nursing and healthcare: theory and practice.* 2nd edn. New York: Wiley Blackwell.

McCleary, N.*, et al.* (2013) 'Active ingredients are reported more often for pharmacologic than non-pharmacologic interventions: an illustrative review of reporting practices in titles and abstracts', *Trials,* 14(146).

McConnachie, A.*, et al.* (2017) 'Birth weight differences between those offered financial voucher incentives for verified smoking cessation and control participants enrolled in the Cessation in Pregnancy Incentives Trial (CPIT), employing an intuitive approach and a Complier Average Causal Effects (CACE) analysis', *Trials,* 18(337).

McCurry, N.*, et al.* (2002) 'Pregnant women's perception of the implementation of smoking cessation advice', *Health Education Journal,* 61(1), pp. 20-31.

McEvoy, R.*, et al.* (2014) 'A qualitative systematic review of studies using the normalization process theory to research implementation processes', *Implementation Science,* 9(2).

McGowan, A.*, et al.* (2010) ''Breathe': the stop smoking service for pregnant women in Glasgow', *Midwifery,* 26(3), pp. e1-e13.

McIntyre, S.A.*, et al.* (2018) *The use of theory in process evaluations conducted alongside randomized trials of implementation interventions: a systematic review*. Translational Behavioral Medicine. Available at: https://academic.oup.com/tbm/advance-article-abstract/doi/10.1093/tbm/iby110/5208274 (Accessed: 10th April 2019).

McLeod, D.*, et al.* (2003) 'The midwife's role in facilitating smoking behaviour change during pregnancy', *Midwifery,* 19(4), pp. 285-297.

McNaughton, R.J. (2017) *Utilising Normalisation Process Theory to understand the patient journey for high-risk individuals participating in the NHS Health Check.* PhD Dissertation thesis. Teesside, Middlesbrough.

McNeill, A.*, et al.* (2015) *Electronic cigarettes: an evidence update. A report commissioned by Public Health England.* London: Public Health England.

Medical Research Council (2000) *A framework for development and evaluation of RCTs for complex interventions to improve health*. London: MRC.

Mejdoubi, J.*, et al.* (2014) 'Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breastfeeding: a randomized controlled trial', *Midwifery,* 30(6), pp. 688-695.

Melloni, E., Pesce, F. and Vasilescu, C. (2016) 'Are social mechanisms usable and useful in evaluation research?', *Evaluation,* 22(2), pp. 209-227.

Messecar, D.C. (2001) 'Evidence-based practice. Smoking cessation interventions for pregnant women to prevent low birth weight: what does the evidence show?', *Journal of the American Academy of Nurse Practitioners,* 13(4), pp. 171-177.

Metters, A. (2018) Jones, S., 19th June

Michie, S.*, et al.* (2005) 'Making psychological theory useful for implementing evidence based practice: a consensus approach', *Quality & Safety In Health Care,* 14(1), pp. 26-33.

Michie, S. and Prestwich, A. (2010) 'Are interventions theory-based? Development of a theory coding scheme', *Health Psychology,* 29(1), pp. 1-8.

Michie, S.*, et al.* (2013) 'The Behavior Change Technique Taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions', *Annals of Behavioral Medicine,* 46(1), pp. 81-95.

Michie, S., van Stralen, M.M. and West, R. (2011) 'The behaviour change wheel: A new method for characterising and designing behaviour change interventions', *Implementation Science,* 6(42).

Michie, S.*, et al.* (2015) 'Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data)', *Health Technology Assessment,* 19(99).

Miles, M.B. and Huberman, A.M. (1994) *Qualitative data analysis: an expanded sourcebook.* 2nd edn. London: Sage.

Milne, E.M.G. and White, M. (2019) E-mail Jones, S., 18th January.

Ministry of Housing Communities and Local Government (2019) *Indices of Multiple Deprivation*. Available at: https://www.gov.uk/government/collections/english-indices-of-deprivation (Accessed: 31st January 2020).

Moore, G.*, et al.* (2014) *Process evaluation of complex interventions*: UK Medical Research Council. Available at: https://mrc.ukri.org/documents/pdf/mrc-phsrn-process-evaluation-guidance-final/ (Accessed: 10th April 2019).

Moore, G.F.*, et al.* (2015) 'Process evaluation of complex interventions: Medical Research Council guidance', *British Medical Journal,* 350(h1258).

Moores, C.J.*, et al.* (2017) 'CONSORT to community: translation of an RCT to a large-scale community intervention and learnings from evaluation of the upscaled program', *BMC Public Health,* 17(918).

Morden, A.*, et al.* (2015) 'Introducing evidence through research “push” using theory and qualitative methods', *Qualitative Health Research,* 25(11), pp. 1-16.

Morriss, R. (2008) 'Implementing clinical guidelines for bipolar disorder', *Psychology and Psychotherapy: Theory, Research and Practice,* 81(4), pp. 437-458.

Murray, E.*, et al.* (2010) 'Normalisation process theory: a framework for developing, evaluating and implementing complex interventions', *BMC Medicine,* 8(63).

Murray, E.*, et al.* (2011) 'Why is it difficult to implement e-health initiatives? A qualitative study', *Implementation Science,* 6(6).

Murray, E., May, C. and Mair, F. (2010) 'Development and formative evaluation of the e-Health Implementation Toolkit (e-HIT)', *BMC Medical Informatics and Decision Making,* 10(61).

My Virtual Medical Centre (2002-2018) *Cognitive-Behavioural Therapy for quitting smoking*. Australia. Available at: https://www.myvmc.com/?s=cbt&cat=0&sentence=1 (Accessed: 16th May 2019).

National Health Service (2012) *Stoptober: 'Because there's only one YOU'*. Available at: https://www.nhs.uk/oneyou/stoptober/home#OeG11IlTAsm82FAH.97 (Accessed: 17th May 2019).

National Health Service (2014a) *Five year forward view*: Health Education England, Monitor, Public Health England, Care Quality Commission, Trust Development Authority. Available at: http://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf (Accessed: 23rd May 2019).

National Health Service (2014b) *No Smoking Day: 'V for victory'*. Available at: http://www.nosmokingday.org.uk/ (Accessed: 17th May 2019).

National Health Service (2016) *Using the NHS: About the NHS: NHS Trusts and Authorities*. Available at: https://www.nhs.uk/using-the-nhs/about-the-nhs/nhs-authorities-and-trusts/ (Accessed: 7th February 2019).

National Health Service (2019) *NHS Long Term Plan*. Available at: https://www.longtermplan.nhs.uk/online-version/ (Accessed: 10th April 2019).

National Health Service (N.d.) *NHS England and NHS Improvement come together*. Available at: https://www.nhs.uk/NHSEngland/thenhs/about/Pages/authoritiesandtrusts.aspx (Accessed: 18th May 2019).

National Institute for Health and Care Excellence (2007) *Behaviour change: the principles for effective interventions*. London: NICE.

National Institute for Health and Care Excellence (2008) *Public health guidance 10: Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities*. London: NICE.

National Institute for Health and Care Excellence (2010) *Public health guidance 26: Quitting smoking in pregnancy and following childbirth*. London: NICE. Available at: http://guidance.nice.org.uk/PH26.

National Institute for Health and Care Excellence (2012) *NICE public health guidance on tobacco harm reduction evidence reviews*. London: Cedar. Available at: https://www.nice.org.uk/guidance/ph45/resources/tobacco-harm-reduction-evidence-reviews.

National Institute for Health and Care Excellence (2013a) *Public health guidance 26 (update): Quitting smoking in pregnancy and following childbirth*. London: NICE. Available at: https://www.nice.org.uk/guidance/ph26/evidence/review-decision-2013-pdf-546109741 (Accessed: 18th May 2019).

National Institute for Health and Care Excellence (2013b) *Public health guidance 48: Smoking: acute, maternity and mental health services*. London: NICE. Available at: https://www.nice.org.uk/guidance/ph48/chapter/1-recommendations.

National Institute for Health and Care Excellence (2017) *NICE Pathway: PH 26 Stopping smoking in pregnancy and after childbirth*. London: NICE. Available at: https://pathways.nice.org.uk/pathways/smoking#path=view%3A/pathways/smoking/stopping-smoking-in-pregnancy-and-after-childbirth.xml&content=view-index.

National Institute for Health Research (2015) *INVOLVE: National Institute for Health Research (NIHR)-wide learning and development for public involvement: working group report and recommendations*. Available at: https://www.invo.org.uk/posttypepublication/national-institute-for-health-research-nihr-wide-learning-and-development-for-public-involvement-working-group-report-and-recommendations-2015/ (Accessed: 10th April 2019).

National Institute for Health Research (2016) *Smoking bans improve cardiovascular health and reduce smoking-related deaths*. NIHR Signals: NIHR. Available at: https://discover.dc.nihr.ac.uk/portal/article/4000258/smoking-bans-improve-cardiovascular-health-and-reduce-smoking-related-deaths (Accessed: 23rd May 2019).

National Institute for Health Research (2017) *Better Beginnings: improving health in pregnancy*. Available at: https://www.dc.nihr.ac.uk/themed-reviews/health-in-pregnancy-research.htm (Accessed: 10th April 2019).

Naylor, P.-J., Adams, J.S. and McNeil, D. (2002) 'Facilitating changes in perinatal smoking', *Canadian Journal of Public Health,* 93(4), pp. 285–290.

Nelson, B. (2013) 'Region pioneers new drive to help pregnant women stop smoking', *The Northern Echo*, 19th December. Available at: http://www.thenorthernecho.co.uk/news/10885294.Region_pioneers_new_drive_to_help_pregnant_women_stop_smoking/?ref=rss (Accessed: 17th May 2019).

NHS Digital (No date) *Statistics on Women's Smoking Status at Time of Delivery - England, Quarter 3, 2011-12*: NHS Digital. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-women-s-smoking-status-at-time-of-delivery-england/statistics-on-women-s-smoking-status-at-time-of-delivery-england-quarter-3-2011-12 (Accessed: 26th March 2019).

NHS England (2008) *Using the Commissioning for Quality and Innovation (CQUIN) framework*. London: Department of Health. Available at: https://webarchive.nationalarchives.gov.uk/20130104193214/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_091443 (Accessed: 17th May 2019).

NHS England (2016) *Leading Change, Adding Value: a framework for nursing, midwifery and care staff*. Available at: https://www.england.nhs.uk/wp-content/uploads/2016/05/nursing-framework.pdf (Accessed: 10th April 2019).

NHS England, O'Connor, D. and Gould, D. (2014) *Saving Babies Lives: reducing stillbirth and neonatal death: a care bundle*. Available at: https://www.england.nhs.uk/wp-content/uploads/2016/03/saving-babies-lives-car-bundl.pdf (Accessed: 10th April 2019).

Nutbeam, D. (2002) 'Effective health promotion programmes', in Pencheon, D.*, et al.* (eds.) *Oxford Handbook of Public Health Practice*. Oxford: Oxford University Press.

O'Gorman, C. (2011) 'Dying for a cigarette', *Midwives: The official journal of the Royal College of Midwives,* (7), pp. 32-34.

O'Cathain, A.*, et al.* (2015) 'Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers', *BMC Pilot and Feasibility Studies,* 1(32).

O'Cathain, A.*, et al.* (2013) 'What can qualitative research do for randomised controlled trials? A systematic mapping review', *BMJ Open,* 3(e002889).

O'Neill, G.*, et al.* (2015) 'Can a theoretical framework help to embed alcohol screening and brief interventions in an endoscopy day-unit?', *Frontline Gastroenterology,* 7(1).

Ogden, J. and Cornwell, D. (2010) 'The role of topic, interviewee and question in predicting rich interview data in the field of health research', *Sociology of Health and Illness,* 32(7), pp. 1059-1071.

Ogilvie, D.*, et al.* (2011) 'Evaluability of complex public health interventions: Five questions for researchers, funders, and policymakers', *Milbank Quarterly,* 89(2), pp. 206-225.

Ong, B.N.*, et al.* (2014) 'Changing policy and practice: making sense of national guidelines for osteoarthritis', *Social Science & Medicine,* 106(April), pp. 101-109.

Ormston, R.*, et al.* (2015) 'quit4u: the effectiveness of combining behavioural support, pharmacotherapy and financial incentives to support smoking cessation', *Health Education Research,* 30(1), pp. 121–133.

Orton, L.*, et al.* (2017) 'Putting context centre stage: evidence from a systems evaluation of an area based empowerment initiative in England', *Critical Public Health,* 27(4), pp. 1-13.

Papoutsi, C.*, et al.* (2016) 'Challenges for implementation science', in Raine, R.*, et al.* (eds.) *Challenges, solutions and future directions in the evaluation of service innovations in health care and public health*. NIHR journals library: Health Services Delivery Research, pp. 121-132.

Parker, D.R.*, et al.* (2006) 'Feasibility, cost, and cost-effectiveness of a telephone-based motivational intervention for underserved pregnant smokers', *Nicotine and Tobacco Research,* 9(10), pp. 1043-1051.

Patel, B.*, et al.* (2018) 'What drives adoption of a computerised, multifaceted quality improvement intervention for cardiovascular disease management in primary healthcare settings? A mixed methods analysis using Normalisation Process Theory', *Implementation Science,* 13(140).

Pawson, R. (2006) *Evidence-based policy: a realist perspective.* London: Sage.

Pawson, R. and Tilley, N. (1997) *Realistic evaluation.* London: Sage.

Pawson, R. and Tilley, N. (2004) *Realist evaluation.* London. Available at: http://www.communitymatters.com.au/RE_chapter.pdf (Accessed: 11th April 2019).

Pbert, L.*, et al.* (2004) 'A community health center smoking-cessation intervention for pregnant and postpartum women', *American Journal of Preventive Medicine,* 26(5), pp. 377-385.

Peters, G.-J.Y., Ruiter, R.A.C. and Kok, G. (2013) 'Threatening communication: a critical re-analysis and a revised meta-analytic test of fear appeal theory', *Health Psychology Review,* 7, pp. S8-S31.

Press Association (2013) 'Midwives use carbon monoxide test to target pregnant smokers', *Nursing Times*, 19th December. Available at: http://www.nursingtimes.net/home/clinical-zones/midwifery-and-neonatal-nursing/midwives-use-carbon-monoxide-test-to-target-pregnant-smokers/5066616.article (Accessed: 17th May 2019).

Priestley, C. (2013) 'Births at Bishop Auckland suspended', *The Northern Echo*, 5th July. Available at: http://www.thenorthernecho.co.uk/news/10530732.Ambulance_response_times_trigger_temporary_MLU_closure/ (Accessed: 18th May 2019).

Prochaska, J. and DiClemente, C. (1983) 'Stages and processes of self-change in smoking: toward an integrative model of change', *Journal of Consulting and Clinical Psychology,* 51(3), pp. 390-395.

Prusakowski, M.*, et al.* (2011) 'Effect of depression and psychosocial stressors on cessation self-efficacy in mothers who smoke', *Maternal & Child Health Journal,* 15(5), pp. 620-626.

Pryke, M. (2003) 'Situated audiences', in Pryke, M., Rose, G. and Whatmore, S. (eds.) *Using social theory: thinking through research*. London: Sage.

Public Health England (2013) *Every time you smoke your blood gets thick and sticky with toxins*: YouTube [Advertisement]. Available at: https://www.youtube.com/watch?v=c6Ul9QIfBno (Accessed: 18th May 2019).

Public Health England (2015a) *E-cigarettes a new foundation for policy and practice*. London: PHE. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454517/Ecigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf (Accessed: 18th May 2019).

Public Health England (2015b) *Health matters: smoking and quitting in England*. Available at: https://www.gov.uk/government/publications/health-matters-smoking-and-quitting-in-england/smoking-and-quitting-in-england (Accessed: 11th April 2019).

Public Health England (2016) *Making every contact count, MECC: practical resources*. Available at: https://www.gov.uk/government/publications/making-every-contact-count-mecc-practical-resources (Accessed: 4th May 2016).

Public Health England (2019) *Local Tobacco Control Profiles: Smoking at time of delivery*. Available at: https://fingertips.phe.org.uk/profile/tobacco-control (Accessed: 7th February 2019).

QuitManager (2019) Bionical Solutions [online]. Available at: https://www.bionical.com/products/quit-manager (Accessed: 10th April 2019).

Raine, R.*, et al.* (2016) 'Challenges, solutions and future directions in the evaluation of service innovations in health care and public health', *Health Services and Delivery Research,* 4(16).

Rapley, T.*, et al.* (2018) 'Improving the normalization of complex interventions: part 1 - development of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT)', *BMC Medical Research Methodology,* 18(133).

Rawnsley, A. (2018) *General Submission and Examination Regulations for the Award of Higher Degrees by Research – RDC-E. Version 4.* Middlesbrough: Teesside University. Available at: https://unity3.tees.ac.uk/schools/009/RD%20Administrative%20documents/RDC-E%20General%20Examination%20Regulations%20for%20Higher%20Degrees%20by%20Research%202018-19.pdf.

Ritchie, J. and Spencer, A. (2012) 'In pursuit of quality', in Harper, D. and Thompson, A.R. (eds.) *Qualitative research methods in mental health and psycotherapy: a guide for students and practitioners*. Sussex: Wiley-Blackwell.

Ritchie, J. and Spencer, L. (1994) 'Qualitative data analysis for applied policy research', in Bryman, A. and Burgess, R.G. (eds.) *Analyzing qualitative data*. London: Routledge.

Ritchie, J., Spencer, L. and O'Connor, W. (2003) 'Carrying out qualitative analysis', in Ritchie J. and Lewis J. (eds.) *Qualitative research practice: a guide for social sciences students and researchers*. London: Sage.

Robling, M.*, et al.* (2016) 'Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): a pragmatic randomised controlled trial', *Lancet,* 387(10014), pp. 146–155.

Rogers, E.M. (1962) *Diffusion of innovations.* New York: Free press.

Rogers, E.M. (2003) *Diffusion of innovations.* 5th edn. London: Simon & Schuster.

Rogers, P.J. (2007) *New Directions for Evaluation. Theory-based evaluation: reflections ten years on: theory-based evaluation: past, present, and future* Available at: https://doi.org/10.1002/ev.225.

Rose, G. (1982) *Deciphering sociological research.* London: Macmillan.

Rousseau, D.M. (2011) 'Reinforcing the micro/macro bridge: organizational thinking and pluralistic vehicles', *Journal of Management,* 37(2), pp. 429-442.

Royal College of General Practitioners and Cancer Research, U.K. (2017) *Electronic cigarettes*: Cancer Research UK. Available at: http://www.cancerresearchuk.org/health-professional/learning-and-ways-we-can-support-you/cruk-rcgp-partnership/e-cigarette-statement (Accessed: 21st December 2017).

Royal College of Midwives (2010) 'Midwives to measure pregnant women's carbon monoxide levels', *Midwives*, June 23rd.

Royal College of Midwives (2011) 'Dying for a cigarette', *Midwives*, November 14th.

Royal College of Midwives (2015) 'Royal College of Midwives supports pregnant women being offered carbon monoxide (CO) testing', *Midwives*, October 16th.

Royal College of Midwives (N.d.) *Home: Promoting: Professional practice: Midwives and public health: How is the RCM involved? Stopping smoking in pregnancy*. Available at: https://www.rcm.org.uk/promoting/professional-practice/midwives-public-health/ (Accessed: 26th March 2019).

Royal College of Obstetricians and Gynaecologists (2013) *Small-for-gestational-age fetus, investigation and management (Green-top guideline No. 31)*. Available at: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg31/ (Accessed: 18th May 2019).

Royal College of Obstetricians and Gynaecologists (2014a) *Information for you: having a small baby*. Available at: https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-having-a-small-baby.pdf (Accessed: 12th March 2019).

Royal College of Obstetricians and Gynaecologists (2014b) *Small-for-gestational-age fetus, investigation and management (Green-top guideline No. 31) - Updated*. Available at: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg31/ (Accessed: 18th May 2019).

Royal College of Physicians (2016) *Nicotine without smoke: tobacco harm reduction.* London. Available at: https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0 (Accessed: 18th May 2019).

Royal College of Physicians and Tobacco Advisory Group (2010) *Passive smoking in children*. Available at: https://www.rcplondon.ac.uk/sites/default/files/documents/passive-smoking-and-children.pdf (Accessed: 11th April 2019).

Royal College of Physicians and Tobacco Advisory Group (2018) *Hiding in plain sight: Treating tobacco dependency in the NHS*. Available at: https://www.rcplondon.ac.uk/projects/outputs/hiding-plain-sight-treating-tobacco-dependency-nhs (Accessed: 11th April 2019).

Ruggiero, L.*, et al.* (2000) 'The transtheoretical model of smoking: comparison of pregnant and nonpregnant smokers', *Addictive Behaviors,* 25(2), pp. 239-251.

Rushmer, R.K.*, et al.* (2015) 'Research utilisation and knowledge mobilisation in the commissioning and joint planning of public health interventions to reduce alcohol-related harms: a qualitative case design using a cocreation approach', *Health Services and Delivery Research,* 3(33), pp. 1-276.

Rycroft-Malone, J.*, et al.* (2016) 'Collective action for implementation: a realist evaluation of organisational collaboration in healthcare', *Implementation Science,* 11(17).

Rycroft-Malone, J.*, et al.* (2010) 'A realistic evaluation: the case of protocol-based care', *Implementation Science,* 5(38).

Salter, K.L. and Kothari, A. (2014) 'Using realist evaluation to open the black box of knowledge translation: a state-of-the-art review', *Implementation Science,* 9(115).

Sandelowski, M. (2000) 'Whatever happened to qualitative description?', *Research in Nursing & Health,* 23(4), pp. 334-340.

Sandelowski, M. (2018) 'A reluctant but necessary rebuttal to a rebuttal', *Journal of Mixed Methods Research,* 12(4), pp. 1–3.

Sanders, J.*, et al.* (2019) 'Implementation of the Family Nurse Partnership programme in England: experiences of key health professionals explored through trial parallel process evaluation', *BMC Nursing,* 18(13).

Sanders, T., Foster, N.E. and Ong, B.N. (2011) 'Perceptions of general practitioners towards the use of a new system for treating back pain: a qualitative interview study', *BMC Medicine,* 9(49).

Schein, E.H. and Schein, P. (2017) *Organizatinal culture and leadership.* New Jersey: Wiley.

Schloemer, T. and Schröder-Bäck, P. (2018) 'Criteria for evaluating transferability of health interventions: a systematic review and thematic synthesis', *Implementation Science,* 13(88).

Schneider, S.*, et al.* (2010) 'Smoking cessation during pregnancy: a systematic literature review', *Drug and Alcohol Review,* 29 (1), pp. 81–90.

Schön, D. (1987) *Educating the reflective practitioner.* San Francisco: Jossey-Bass.

School for Public Health Research (2016) *SPHR final report: babyClear© smoking cessation during pregnancy*: SPHR. Available at: https://sphr.nihr.ac.uk/research/babyclear/ (Accessed: 12th March 2019).

Segrott, J.*, et al.* (2017) 'An application of extended normalisation process theory in a randomised controlled trial of a complex social intervention: process evaluation of the strengthening families programme (10–14) in Wales, UK', *SSM Population Health,* 3, pp. 255-265.

Sharpe, K.K.*, et al.* (2018) 'Implementing an integrated pathway to care for the dying: is your organisation ready?', *International Journal of Palliative Nursing,* 24(2), pp. 70-78.

Shemeili, S.A.*, et al.* (2016) 'An exploration of health professionals' experiences of medicines management in elderly, hospitalised patients in Abu Dhabi', *International journal of clinical pharmacy,* 38(1).

Shepherd, J. (2014) *How to achieve more effective services: the evidence ecosystem*. Available at: http://orca.cf.ac.uk/69077/1/2014_JPS_What_Works.pdf (Accessed: 11th April 2019).

Shipton, D.*, et al.* (2009) 'Reliability of self reported smoking status by pregnant women for estimating smoking prevalence: a retrospective, cross sectional study', *British Medical Journal,* 339(339), p. b4347.

Shoveller, J.*, et al.* (2016) 'A critical examination of representations of context within research on population health interventions', *Critical Public Health,* 26(5), pp. 487-500.

Silverman, D. (2015) *Interpreting qualitative data.* 5th edn. Los Angeles: Sage.

Sitton-Kent, L. (2016) *East Midlands Academic Health Science network (EMAHSN): Igniting innovation: Implementation paper.* EMAHSN.

Sloan, M.*, et al.* (2016) 'Pregnant women's experiences and views on an "opt-out" referral pathway to specialist smoking cessation support: a qualitative evaluation', *Nicotine & Tobacco Research,* 18(5), pp. 1-6.

Smedberg, J.*, et al.* (2014) 'Characteristics of women who continue smoking during pregnancy: a cross-sectional study of pregnant women and new mothers in 15 European countries', *BMC Pregnancy and Childbirth,* 14(213).

Sobell, L.C. and Sobell, M.B. (2011) *Motivational techniques and skills for health and mental health coaching/counseling*. Available at: https://www.nova.edu/gsc/forms/mi-techniques-skills.pdf (Accessed: 16th May 2019).

Song, F.*, et al.* (2015) *Differences in longer-term smoking abstinence after treatment by specialist or nonspecialist advisors: secondary analysis of data from a relapse prevention trial*. Nicotine & Tobacco Research. Available at: https://academic.oup.com/ntr/article/18/5/1061/2510416 (Accessed: 16th May 2019).

Spangaro, J., Poulos, R.G. and Zwi, A.B. (2011) 'Pandora doesn't live here anymore: normalization of screening for intimate partner violence in Australian antenatal, mental health, and substance abuse services', *Violence and Victims,* 26(1), pp. 130-144.

Spradley, J.P. (1980) *Participant observation.* Fort Worth; London: Harcourt Brace Jovanovich.

Squires, J.E.*, et al.* (2015a) 'Understanding context in knowledge translation: a concept analysis study protocol', *Journal of Advanced Nursing,* 71(5), pp. 1146-1155.

Squires, J.E.*, et al.* (2015b) 'Identifying the domains of context important to implementation science: a study protocol', *Implementation Science,* 10(135).

Stanton, A. and Grimshaw, G. (2013) *Tobacco cessation interventions for young people*. Cochrane Database of Systematic Reviews. Available at:

http://www.cochrane.org/CD003289/TOBACCO_are-there-any-smoking-cessation-programmes-which-can-help-adolescents-to-stop-smoking (Accessed: 1st June 2019).

Steele, G.C.*, et al.* (2019) 'Using exploratory trials to identify relevant contexts and mechanisms in complex electronic health interventions: evaluating the electronic patient-reported outcome tool', *Journal of Medical Internet Research: Formative Research,* 3(1), p. e11950.

Stewart, D. and Klein, S. (2015) 'The use of theory in research', *International Journal of Clinical Pharmacology,* 38(3), pp. 615-619.

Straus, S.E. (2009) *Knowledge translation in health care: moving from evidence to practice.* 1st edn. Oxford: Blackwell Publishing Ltd.

Summers, D. (2009) 'David Cameron warns of 'new age of austerity'', *The Guardian*, 26th April. Available at: https://web.archive.org/web/20090429083220/http:/www.guardian.co.uk/politics/2009/apr/26/david-cameron-conservative-economic-policy1 (Accessed: 16th May 2019).

Sweeney-Magee, M.*, et al.* (2016) 'Assessing the fidelity of delivery of an intervention to increase attendance at the English Stop Smoking Services', *Implementation Science,* 11(166).

Tansella, M. and Thornicroft, G. (2009) 'Implementation science: understanding the translation of evidence into practice', *The British Journal of Psychiatry,* 195(4), pp. 283–285.

Tappin, D.*, et al.* (2015) 'Financial incentives for smoking cessation in pregnancy: randomised controlled trial', *British Medical Journal,* 350, p. h134.

Thompson, A.R. and Chambers, E. (2012) 'Ethical issues in qualitative mental health research', in Harper, D. and Thompson, A.R. (eds.) *Qualitative research methods in mental health and psycotherapy: a guide for students and practitioners*. Sussex: Wiley-Blackwell.

Tierney, E.*, et al.* (2014) 'A critical analysis of the implementation of service user involvement in primary care research and health service development using normalization process theory', *Health Expectations: An International Journal of Public Participation in Health Care & Health Policy,* 19(3), pp. 501-515.

Tong, A., Sainsbury, P. and Craig, J. (2007) 'Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups', *International Journal for Quality in Health Care,* 19(6), pp. 349-357.

Trietsch, J.*, et al.* (2014) 'The challenge of transferring an implementation strategy from academia to the field', *Journal of evaluation in clinical practice,* 20(6), pp. 1162-1171.

Triggle, N. (2017) 'Pub smoking ban: 10 charts that show the impact', *BBC News*, 1st July. Available at: http://www.bbc.co.uk/news/health-40444460 (Accessed: 17th May 2019).

University of Ottawa Heart Institute (2019) *Ottawa Model for smoking cessation*. Available at: https://ottawamodel.ottawaheart.ca/ (Accessed: 16th May 2019).

Ussher, M. (2018) Email Jones, S., 23rd March.

Ussher, M.*, et al.* (2016) 'Dependence and motivation to stop smoking as predictors of success of a quit attempt among smokers seeking help to quit', *Addictive Behaviors,* 53, pp. 175–180.

Valente, T.W. and Rogers, E.M. (1995) 'The origins and development of the diffusion of innovations paradigm as an example of scientific growth', *Science communication,* 16(3), pp. 242-273.

Vera, H. (2016) 'Rebuilding a classic: the social construction of reality at 50', *Cultural Sociology,* 10(1), pp. 3-20.

Vogl, S. (2018) 'Integrating and consolidating data in mixed methods data analysis: examples from focus group data with children', *Journal of Mixed Methods Research*, 13(4), pp. 536-554. Available at: https://journals.sagepub.com/doi/10.1177/1558689818796364 (Accessed: 23rd April 2019).

W.K. Kellogg Foundation (2004) *Logic Model Development Guide*. Michigan. Available at: https://www.bttop.org/sites/default/files/public/W.K.%20Kellogg%20LogicModel.pdf (Accessed: 23rd April 2019).

Walton, M. (2016) 'Expert views on applying complexity theory in evaluation: opportunities and barriers', *Evaluation,* 22(4), pp. 410-423.

Walugembe, D.*, et al.* (2019) 'Sustainability of public health interventions: where are the gaps?', *Health Research Policy and Systems,* 17 (1).

Wanless, D. (2004) *Wanless Report: Securing good health for the whole population*. London: The Stationery Office. Available at: https://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4074426.

Wareing, H. (2018a) Email Jones, S., 8th November.

Wareing, H. (2018b) Telephone call Jones, S., 12th November.

Watson, R.*, et al.* (2011) 'Models of transitional care for young people with complex health needs: a scoping review', *Child: Care Health and Development,* 37(6), pp. 780-791.

Wee, L.-H.*, et al.* (2015) 'Should the threshold for expired-air carbon monoxide concentration as a means of verifying self-reported smoking abstinence be reduced in clinical treatment programmes? Evidence from a Malaysian smokers' clinic', *Addictive Behaviors,* 47, pp. 74-79.

Wellington, J.*, et al.* (2009) *Succeeding with your doctorate.* London: Sage.

Welshman, J. (2010) 'From Head Start to Sure Start: Reflections on policy transfer', *Children & Society,* 24(2), pp. 89–99.

Wenger-Trayner, B.*, et al.* (2017) 'Boundaries and boundary objects: an evaluation framework for mixed methods research'. J*ournal of Mixed Methods Research*, 13(3), pp. 321-338. Available at: https://journals.sagepub.com/doi/abs/10.1177/1558689817732225 (Accessed: 1st June 2019).

Wenger, E. (2009) *Communities of practice: a brief introduction* [online]. Available at: http://www.ewenger.com/theory/ (Accessed: 28th April 2016 2016).

West, R. and McEwen, A. (2012) *Smoking in England Reports: Briefing 8: Stop smoking services: increased chances of quitting*: National Centre for Smoking Cessation and Training (NCSCT). Available at: http://www.ncsct.co.uk/usr/pub/Briefing%208.pdf (Accessed: 23rd April 2019).

Wight, D.*, et al.* (2015) 'Six steps in quality intervention development (6SQuID)', *Journal of Epidemiology and Community Health,* 70(5).

Wikstrom, E.*, et al.* (2019) 'The Safe Hands Study: Implementing aseptic techniques in the operating room: facilitating mechanisms for contextual negotiation and collective action', *American Journal Of Infection Control,* 47(3), pp. 251-257.

Wilkes, S. and Rubin, G. (2009) 'Process evaluation of infertility management in primary care: has open access HSG been normalized?', *Primary Health Care Research & Development,* 10(4), pp. 290-298.

Willis, C.D.*, et al.* (2016) 'Sustaining organizational culture change in health systems', *Journal of Health Organisation and Management,* 30(1), pp. 2-30.

Willmore, M. (2014) Email Jones, S., 25th March.

World Health Organisation (2014) *No Tobacco Day: Raise taxes on tobacco*. Geneva: World Health Organisation [Campaign]. Available at: http://www.who.int/campaigns/no-tobacco-day/2014/event/en/ (Accessed: 17th May 2019).

Wright, N.T. (2001) *Jesus and the victory of God.* London: Society for Promoting Christian Knowledge.

Yousefi, N.R.*, et al.* (2018) 'Social Network Analysis: an example of fusion between quantitative and qualitative methods'. *Journal of Mixed Methods Research*, 14(1), pp. 110-124. Available at: https://journals.sagepub.com/doi/abs/10.1177/1558689818804060?journalCode=mmra (Accessed: 1st June 2019).

Zapka, J.*, et al.* (2004) 'Translating efficacy research to effectiveness studies in practice: lessons from research to promote smoking cessation in community health centers', *Health Promotion Practice,* 5 (3), pp. 245-255.

Zimmerman, G.L., Olsen, C. and Bosworth, M.F. (2000) 'A 'Stages of Change' approach to helping patients change behavior', *American Family Physician,* 61(5), pp. 1409-1416.

Chapter 11 APPENDICES

11.1 Publications and Presentations

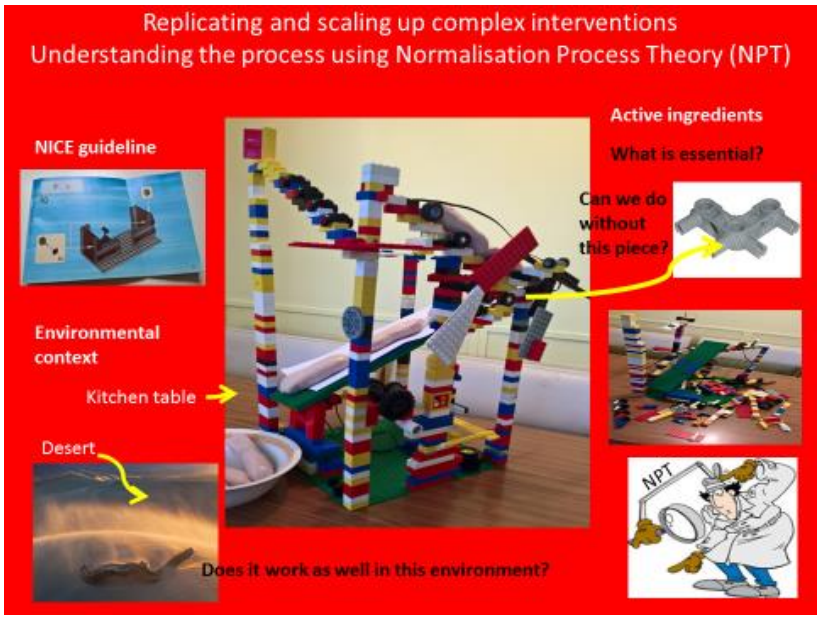
1. Bell, R., et al. (2018) Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation. Tobacco Control. Available at: http://tobaccocontrol.bmj.com/content/early/2017/02/10/tobaccocontrol-2016-053476 (Accessed: 20th May 2019)

2. Jones, S., *et al.* (2019) 'What helped and hindered implementation of an intervention package to reduce smoking in pregnancy: process evaluation guided by normalization process theory', *BMC Health Services Research,* 19(1), p. 297.

3. 3-minute thesis competition

Figure 11-1: Winning slide from 3-minute thesis competition

Post-Graduate Conference, Teesside University, May 31st, 2017



Here we have model of a complex intervention – a sausage-making machine!

The guideline seems clear, in the laboratory the environment is clean and conducive, and it's working well, producing tasty sausages.

Now to take it out into clinical situations, onto the frontline, and continue production in a variety of places where sausages are really needed.

The environment is no longer clean and well-controlled. Production falters. An apparently insignificant 'cog' turns out to be a really important ingredient (but nobody knew) – initially the sausage quality deteriorates, then the machine no longer works at all, no more tasty sausages. NPT can help explain this conundrum – why the machine failed to produce the expected outcomes.

11.2 Additional information to supplement the thesis

11.2.1 Stopping smoking in pregnancy

Introduction

This appendix sets out the recommendations from NICE PH guidance (2010) that are incorporated into the intervention; then it considers the intervention components themselves, how they are applied in practice, barriers to their operation and how they are expected to change behaviour.

Recommendations in NICE (2010)

These are the recommendations from NICE PH Guidance (2010) that are encapsulated within the babyClear© intervention package - beyond what was happening in practice:

Recommendation 1

- CO testing with low cut off point
- Refer all women who smoke, have quit in last 2 weeks or CO above 7ppm.
- Advise those who say they do not smoke but have raised CO reading to check gas boilers etc.
- Repeat referrals to SSS at future appointments if not taken up
- Record and use feedback loop.

Recommendation 3

- SSS to ring twice then follow up with letter and inform midwife of outcome
- SSS to be flexible in their approach to engaging pregnant smokers.

Recommendation 4

- Introduces the idea of financial incentives but observes that evidence of effectiveness does not exist yet
- Encourages SSS staff to include other family members
- Encourages SSS staff to use the CO monitoring as positive reinforcement to quit
- Brings in biochemical validation as standard.

Recommendation 6

- Aims at reducing the barriers for those within demographic of highest smokers e.g. accessibility, culturally relevant,
- In practice this might mean flexible times and locations, tailored advice etc.

Recommendation 7

- Focuses on reducing smoking in the household e.g. by family and partners.

Recommendation 8

- Every midwife to be SS trained to a certain level including accredited training in use of CO monitors
- Cutting down not recommended
- Training must tackle barriers to delivering SS intervention e.g. fear of damaging professional relationship.

Implementing complex SS interventions in pregnancy

NICE PH Guidance (2010) drew together all the evidence to date, however the issue that was highlighted in NE England was that it tended not to be fully implemented (Beenstock *et al*., 2012). This failure to fully implement guidance was not an unusual situation, restricted to England, but also found elsewhere (Cluss, Levine and Landsittel, 2011; Chamberlain *et al.*, 2013).

Initially there was a lack of effectiveness of initiatives in the 1980s and 1990s followed by the development of various combinations of interventions in a 'trial and error' approach (Batten *et al*., 1999; DH, 1998; Graham, 1976; Kramer, 1987; Prochaska & DiClemente, 1983). The theoretical bases for SS interventions in pregnancy have become more secure over time (NICE, 2010). Nevertheless, as explored in Chapter 2, trials measure effectiveness e.g. number of quits, without explaining the circumstances behind the number. Why has it increased or decreased? How was the intervention delivered? What aspects of delivery affected the number? What is happening in women's and staff lives that changed patterns of behaviour? Why do some systems appear to facilitate effectiveness? The systems and contexts into which complex interventions are implemented remain less well understood due to a lack of qualitative papers reporting women's and staff views on SS interventions (Moore *et al.*, 2014). More, high-quality, process evaluations are required to address these questions (Ruggiero *et al.*, 2000; McCurry *et al.*, 2002; McLeod *et al.*, 2003).

Foundational theory

Stop smoking models for the general smoking population are based on the Transtheoretical Model (TTM) (Prochaska and DiClemente, 1983; Ruggiero *et al.*, 2000). For pregnant women, the recommended model is outlined in NICE PH Guidance (2010).

Requirement for specificity

SS interventions for pregnant women, by definition, are required to match these women's very specific situations. Although methods can be borrowed from general SS interventions, they must also go above and beyond them, to be responsive to this particular group (Bryce *et al.*, 2009). This is illustrated by the disparity between pregnant women's oft expressed desire to quit and what actually happens (Baxter *et al.*, 2010). At the time of pregnancy smoking is usually well established (Borman, Wilson and Maling, 1999). Beyond the fact of their pregnant state many women are not considering quitting (Lawrence and Haslam, 2007; Baha and Le Faou, 2009; Bryce *et al.*, 2009; McGowan *et al.*, 2010). Moving them to the next stage of readiness, as conceptualised by the TTM, may need to be the focus of the intervention (Ruggiero *et al.*, 2000). In particular, interventions need to work for the women who begin to quit, as well as those who do not, in the immediate days and weeks following conception (Higgins *et al*., 2006). Indeed, those who continue to smoke in the first fortnight while attempting to quit, were found to be more likely to relapse in the longer term (Higgins *et al*., 2006). Dedicated, maternity-based, SSS are attractive to this group and may go some way to breaking down their barriers to engagement and change (Bryce *et al.*, 2009). Given encouragement, it appears that pregnant smokers can be supported to quit in greater numbers, than if that encouragement is not made available (Parker *et al.*, 2006; McGowan *et al.*, 2010; NICE, 2010; Bailey, 2015).

Components of stop smoking interventions

The mechanisms of impact expected from NICE PH Guidance (2010), and written into the babyClear© pathway, are tabulated in Table 1-5 and discussed in section 1.8.5. A selection of these active ingredients have also been written into other intervention packages, including those listed below:

5 As (Ask, Advise, Assess, Assist, Arrange) or similar, for those not ready to quit, are the basis for many interventions e.g. SUCCESS – (Ayadi *et al.*, 2006; Lumley *et al.*, 2009; Albrecht *et al.*, 2011)

TIPS (5 As plus tailoring, practical assistance etc.) - (Bailey, 2015)

Ottawa Model for Smoking Cessation, Canada (University of Ottawa Heart Institute, 2019)

'Baby and Me' – (Gadomski *et al.*, 2011)

BREATHE, CATCH - (McGowan *et al.*, 2010; Sloan *et al.*, 2016)

SCRIPT - (Parker *et al.*, 2006)

STOP - (Cluss, Levine and Landsittel, 2011)

The interventions focus on one specific element or many e.g.

- Information booklets (Bullock *et al.*, 2009)
- Telephone/face-to-face/text (Parker *et al.*, 2006); without frequent face-to-face contact perhaps lose some of the value of frequent CO testing and encouragement (McGowan *et al.*, 2010)
- Extra support – frequency, accessibility, peer/PH nurse/ midwife e.g. maternity care assistant/midwife - (McGowan *et al.*, 2010); midwife, frequency, home, partner - (McLeod *et al.*, 2003; Bailey, 2015)
- Feedback loops, monitoring quit rates - (Messecar, 2001)
- Pharmacological as well as behavioural elements (NRT not proven and cannot be trialled in pregnancy due to ethical constraints, journey of thinking through seen in NICE PH Guidance (2007; 2010); direct provision of NRT investigated, GPs reluctant to prescribe NRT to pregnant women, outcomes of using NRT look positive - (Bryce *et al.*, 2009; Galloway, 2012).

Recently the British Government has opted for the Ottawa Model as the way forward for SSS as a whole, as set out in the NHS 10-year Plan (NHS, 2019).

Effectiveness of elements of stop smoking interventions for pregnant women

In the following paragraphs I discuss the key active ingredients of SS interventions, recommended in NICE PH Guidance (2010), and found in the babyClear© pathway. I expand on the information provided in section 1.12 in terms of the evidence regarding effectiveness. Then I consider the literature on how this knowledge might be applied in practice.

Smoking status

An important systematic change that is required to meet NICE PH Guidance (2010) recommendations 1 and 4 is measuring/recording smoking status. Measuring smoking status accurately is an area of debate (NICE, 2010). There are two biochemical measures: cotinine and carbon monoxide (NICE, 2010). Cotinine can be detected in saliva and urine and carbon monoxide in expired air; however, cotinine readings, while more accurate than CO, are not always reliable e.g. due to smoking infrequently or breathing second-hand smoke (NICE, 2010). Importantly, CO monitoring has been reported as both acceptable and welcomed by pregnant smokers (Cluss, Levine and Landsittel, 2011; Sloan *et al.*, 2016).

Self-report of smoking is still used in some studies but compared with biochemical markers is known to be inaccurate (Kelley, Bond and Abraham, 2001; Lawrence *et al.*, 2003; Joseph *et al.*, 2009; Albrecht *et al.*, 2011). Bauld *et al*. (2012) carried out a large, pilot study of pregnant women's (n=3712) referral data. They used 4 ppm as the carbon monoxide cut-off level and identified two specific issues: under reporting of smoking status during pregnancy, and discrepancy between cotinine levels and carbon monoxide test results, suggesting that not all smokers were picked up by the carbon monoxide test. Other authors have also highlighted disagreement over the cut off level (3ppm - 10ppm) for carbon monoxide for definition of a smoker (Galloway, 2012; Wee *et al.*, 2015). NICE PH Guidance (2010) agrees that the appropriate cut-off for referral is unclear. These uncertainties send out confused messages to women and midwives; resulting in midwives being unsure which clinical pathway for their mothers to follow (Beenstock *et al.*, 2012).

Opt-out referral

A second change, required to meet recommendation 1, is the introduction of an opt-out referral system. NICE PH Guidance (2010) simply states to use 'local arrangements', e.g. there is no deadline for contact or specific requirements attached (p8). Opt-out has the advantage that all pregnant smokers are approached about their smoking behaviour and ensures that they receive information as a minimum intervention, possibly via post if the service has been unable to contact them by telephone (McGowan *et al.*, 2010). Potentially, with opt-out, they can also be offered other methods of support via the SSS, depending on their level of engagement (McGowan *et al.*, 2010). Although women often did not make themselves easily available or contactable, they did not object to the services' attempts to reach them (Baha and Le Faou, 2009; McGowan *et al.*, 2010). However, opt-out did not ensure that they bought into the process, as even though the referral rate increased, the quit rate did not (Bauld *et al.*, 2012).

Opt-out referral did not move women forward to a stage of readiness or motivate them to quit, suggesting that interventions require a parallel initiative to increase motivation, as well as opt out referrals to SS services (Baha and Le Faou, 2009; Bauld *et al.*, 2012). There is then one more step that requires establishing, the referral pathway must be secure enough to pick up the women following referral, or they will be less likely to carry through to a quit (Sloan *et al.*, 2016). This could be considered a 'nudge' towards a certain type of behaviour, but as Blumenthal-Barby & Burroughs (2012) point out, it should only be used when it pushes people towards a greater benefit. Not all commentators are convinced this is the case (see Feminist Perspective below). Nevertheless, NICE PH Guidance is clearly in favour of opt-out and satisfied that ethical considerations are met (2010). However, contacting this

elusive population uses many resources and raises the question of cost-effectiveness (McGowan *et al.*, 2010; Bauld *et al.*, 2012; Sloan *et al.*, 2016).

Intensity of intervention

An intensification of interaction between SS services and referred women is recommended (NICE, 2010). The recommendation asks services to make multiple contacts following referral and to pursue women through many avenues including telephone, face-to-face and letters. Although Lumley *et al*. (2009), in their Cochrane review, were not able to identify an intensity effect, they postulated that this may be due to a lack of process evaluation to explain the intricacies of the outcomes. Many studies have concluded that unless the dose is sufficient, the effect will be too low (Ershoff *et al.*, 1999; Lando *et al.*, 2001; Pbert *et al.*, 2004; Campbell *et al.*, 2006; Lawrence and Haslam, 2007; Moore *et al.*, 2014; Bailey, 2015). In 2013, in a more recent Cochrane review, it was established that there was an intensity effect, but it was not simple to establish as it varied according to many factors (Chamberlain *et al.* 2013). Learning from past efforts, some Scottish researchers have been building in more contacts to increase effectiveness with promising results (Bryce *et al.*, 2009; McGowan *et al.*, 2010).

Counselling and motivational interviewing

Earlier studies of one-to-one counselling were found not to be effective in a meta-analysis by Kelley *et al*. (2001), however they hypothesise that this might be to do with the counselling technique, or counsellor's attitude, raising negative feelings. With changes to techniques and attitudes this finding does appear to have been reversed (NICE, 2010). For example, McGowan *et al*. (2010) found even telephone-based counselling, with face-to-face first and last meetings with specialist stop smoking midwives, to be effective. Motivational interviewing is an approach that has been found to be effective in supporting smokers to quit; and is specifically recommended by NICE PH Guidance (2010) for use with pregnant smokers. It comes from the standpoint of empowerment; again, the counsellor expresses empathy then uses 5 thought-provoking, confidence-raising approaches:

- Asking permission
- Eliciting/evoking change talk
- Exploring importance and confidence
- Open-ended questions
- Reflective listening

(Sobell and Sobell, 2011)

The client is encouraged to find answers for themselves, which suit their life and circumstances; the counsellor does not give advice (Sobell and Sobell, 2011). MI has been used successfully - as one element - in SS in pregnancy interventions including TIPS and BREATHE (McGowan *et al.*, 2010; Bailey, 2015). Motivational interviewing was also central to the methods employed by Bryce *et al*. (2009) who used it with good effect. The potential cost savings simply from using the more established, evidence-based models of counselling (e.g. 5 As) still look very persuasive (Ayadi *et al.*, 2006; Parker *et al.*, 2006; Cluss, Levine and Landsittel, 2011).

Cognitive behavioural therapy (CBT)

One method of supporting individual behaviour change that has become popular is cognitive behavioural therapy (CBT); an umbrella term for therapies based on cognition (My Virtual Medical Centre (MyVMC), 2002-2018). Cognitive therapy was pioneered by Beck (1967). Various forms of CBT have since been tested widely with positive results; often used in depression and anxiety disorders, it is also used in smoking cessation (MyVMC, 2002-2018; Stanton and Grimshaw, 2013). The foundation of the approach is one of changing faulty beliefs, especially those that lead to harmful behaviours (Beck Institute, 2016). The therapist takes an empathetic approach and seeks to build rapport with the client, identify the underlying beliefs that create the thoughts that trigger the feelings, which provoke the unhelpful behaviours (My VMC, 2002-2018). It uses goal-setting with achievable short, mid and long-term targets (MyVMC, 2002-2018). When counselling smokers, alternative ways of coping with stress are promoted, enabling recognition of triggers and cues, alongside greater understanding and development of new beliefs through health education (MyVMC, 2002-2018). NICE PH Guidance (2010) specifically recommends use of CBT for quitting in pregnancy.

Employing CBT takes motivational interviewing a step further. Both CBT and motivational interviewing link back to the smoker's stage of change; the therapist or counsellor gently elicits information that indicates where the client is up to in their thinking about changing their behaviour (Zimmerman, Olsen and Bosworth, 2000; Sobell and Sobell, 2011). Although the effectiveness of CBT has been established, as discussed, a recent Cochrane review found no significant difference to usual care (Chamberlain *et al.*, 2013). Reviewers hypothesised that there was insufficient trial evidence available to ascertain its effectiveness confidently (Chamberlain *et al.*, 2013). Some researchers found it improved postpartum relapse rates (El-Mohandes *et al.*, 2011). A number of recent studies have begun to incorporate CBT, although it is likely that specialist HCPs with sufficient skills will be required (Joseph *et al.*, 2009; Albrecht *et al.*, 2011). However, reports on its effectiveness have been mixed,

suggesting that it may be the synergistic effects of multiple elements of an intervention that are crucial to effectiveness (Baha and Le Faou, 2009; Joseph *et al.*, 2009; Albrecht *et al.*, 2011).

Goal-setting

This has become implicit within the guidance, as variables that are submitted to government to monitor SSS activity and outcomes include them e.g. setting a quit date and 4-week quit rates, many of which are used to calculate the Local Tobacco Control Profiles (NICE, 2010; PHE, 2019). No other goals are specifically mentioned; however, some practitioners are more proficient at supporting women to set goals than others (NICE, 2010; Lorencatto *et al.*, 2016). There is no reference to women using CO monitoring as a way to set personal goals and increase their motivation.

Use of NRT in pregnancy

NRT is a standard treatment for stopping smoking; however only some forms of NRT are recommended for use in pregnancy (NICE, 2010). The use of NRT has been controversial, with uncertainty around any danger to the developing fetus from nicotine (Ershoff *et al.*, 1999; Bull, 2007, p185; Lawrence and Haslam, 2007). In more recent years nicotine has been seen as less damaging than the other chemicals inhaled while smoking (Lumley *et al.*, 2004; Lawrence and Haslam, 2007; Galloway, 2012). Sufficient evidence had accumulated by 2008 for NICE to change the recommendations to allow use of some types of NRT in pregnancy (NICE, 2008). Current guidance (NICE, 2010) continues to state that neither varenicline (a nicotine receptor stimulant) nor bupropion (an atypical antidepressant), both used with the general smoking population, should be given to pregnant (or breastfeeding) women. As a result, some HCPs and women remain wary of providing or using NRT in pregnancy (Bull, 2007; Bryce *et al.*, 2009). Very recently electronic cigarettes have become widely available and recommendations for their use are beginning to be published (Britton and Bogdanovica, 2014; RCP, 2016). However, their safety for use in pregnancy remains unclear and equivocal, with little research in this regard, as it would be unethical to run trials in case of any adverse effects; the recommendation is simply not to use them as the effects are unknown (Britton and Bogdanovica, 2014; RCP, 2016).

Use of financial incentives

The introduction of financial incentives is a controversial idea that has been trialled in the UK at different times over recent years (McGowan *et al.*, 2010; Chamberlain *et al.*, 2013; Boyd and Sinclair, 2015; Tappin *et al.*, 2015). There do seem to be some promising results, which

has encouraged further experimentation in Greater Manchester, where an enhanced service is being implemented, similar to babyClear©, with some additional elements, including financial incentives (Ussher, 2018). Outcomes for this study, commencing in January 2019, are awaited.

Harm reduction vs quitting

Quitting is the recommended approach (see above - Recommendation 8). Harm reduction by cutting down the number of cigarettes smoked, rather than completely quitting, is a hotly debated topic (NICE, 2010). Harm reduction has been accepted as an improved outcome; bearing in mind that the long-term effect of NRT in pregnancy is not known (Jaakkola, Zahlsen and Jaakkola, 2001; Cluss, Levine and Landsittel, 2011; Britton and Bogdanovica, 2014). However, others would argue that only reducing smoking makes women more vulnerable to relapse (Higgins *et al.*, 2006; NICE, 2010). It is unclear from a recent review if the 'quitting only' message came in with NICE PH Guidance in 2010 or if it pre-dates it (Flemming *et al.*, 2013; Graham *et al.*, 2014). However, the messages and societal norms at the time of the earlier included papers were quite different in some respects to the present, as seen by recent legislation e.g. ban in enclosed public places, in cars (DH, 2006; DHSC, 2015). The authors recognise this to some extent but argue that endorsement of cutting down has been a consistent theme throughout (Graham *et al.*, 2014).

Graham *et al.* (2014) suggest the best way to deal with harm reduction vs quitting is to acknowledge the disparate views and set up services that support pregnant women to quit gradually, where necessary, and even goes so far as to recommend cutting down as an end in itself. Even though Lindson-Hawley and colleagues (2013; 2016) conclude, in line with NICE PH Guidance 48 (2013b) and 26 (2010), that abrupt, rather than gradual, quitting improves outcomes with regard to relapse. With sustainability of quit status for the woman postpartum a major concern, SS interventions during pregnancy, ideally lay the foundations that will also lead to a permanent quit (Lando *et al.*, 2001; Cluss, Levine and Landsittel, 2011; Gadomski *et al.*, 2011; Jones *et al.*, 2016; Kwasnicka *et al.*, 2016). The focus of the babyClear© intervention package is on behaviour change for the duration of pregnancy (Table 1-5), however, if it (and others like it) can be adjusted to reduce postpartum relapse, this would be of great benefit.

Follow up

It is recommended that follow up systems should be characterised by flexibility and coordination (NICE, 2010). Flexibility refers to their ability to encompass the needs of

pregnant smokers e.g. accessibility, tailored to individual needs, convenient, comfortable (NICE, 2010). Various studies have tried out combinations of frequency, regularity and setting of follow up via different media and locations (Bryce *et al.*, 2009; Baxter *et al.*, 2010; McGowan *et al.*, 2010; Gadomski *et al.*, 2011). Some are more intense with 24-hour telephone support, feedback routes, and/or multiple informal contacts (Bullock *et al.*, 2009; Cluss, Levine and Landsittel, 2011). Bailey (2015) was working in a rural setting, with great difficulty of access; however, offering four, monthly consultations at the same time as antenatal appointments, with telephone support by the same specialist and an opportunity for extra appointments if requested, improved outcomes. Others have offered follow up that goes beyond the quit, to mitigate relapse (Bryce *et al.*, 2009).

Location of follow up is another key issue. NICE PH Guidance (2010) does not recommend a specific setting, although there are hints towards the benefits of offering a choice of settings, including home and clinic-based options. A peripatetic service where the client has choice of time and place was preferred (Bryce *et al.*, 2009; Gadomski *et al.*, 2011). Home visits do appear to improve outcomes, however from a staff perspective, many studies report on the elusive nature of this population, even with extensive efforts to contact them (Joseph *et al.*, 2009; McGowan *et al.*, 2010; NICE, 2010; Bauld *et al.*, 2012; Sloan *et al.*, 2016).

Coordination is another key feature for effectiveness; requiring active integration of SS and maternity services (Bryce *et al.*, 2009). It is important to women that there is a clearly defined pathway between services and good inter-organisational communication; where this was absent it was detrimental to women's outcomes (Sloan *et al.*, 2016). Coordination, flexibility and tailoring of services are important aspects for effective follow up (Borland *et al.*, 2013).

Partner and family support

Recommendation 7 specifically focuses on the partner's smoking status and the need to support them to quit too (NICE, 2010). Family, friends and partners offer social support; their views and smoking behaviours are highly influential in the life of the pregnant smoker (McBride *et al.*, 2004; Ma *et al.*, 2005; Gage, Everett and Bullock, 2007; Lawrence and Haslam, 2007; Koshy *et al.*, 2010; Flemming *et al.*, 2015). When SSS tried to encourage partners to be better supports themselves, they failed to make a difference (McBride *et al.*, 2004). The authors hypothesised this was due to the level of relational dysfunction between couples, rather than any fault with the intervention (McBride *et al.*, 2004). Lack of trial evidence meant that Chamberlain *et al*. (2013) could not say with certainty that partner support helped women quit. However, using qualitative/mixed methods, this continues to be identified as a significant factor (Lagan and Casson, 2010; Flemming *et al.*, 2015). Smoking

status of others in the household is also referred to in Recommendation 7 (NICE, 2010). The evidence points to the importance of peer, family, friends and social support; however, the results remain equivocal (Hennrikus *et al.*, 2010; Koshy *et al.*, 2010). Into this sensitive situation midwives report that they have little opportunity to engage with partners within appointment times, potentially supporting the use of HCP assistants in this role (Bull, 2007).

Cost-effectiveness of SS interventions

It still appeared to be more cost-effective to make this extra resource – enhanced SSS - available during pregnancy, compared with less intense, non-specialist interventions, such as checking smoking status and offering leaflets (Messecar, 2001; Pbert *et al.*, 2004; Ayadi *et al.*, 2006; Parker *et al.*, 2006; Bullock *et al.*, 2009; NICE, 2010; Bailey, 2015; Song *et al.*, 2015). Although surprisingly Chamberlain *et al*. (2013) found that, "Increasing the frequency and duration of the intervention did not appear to increase the effectiveness" (p3). This may be a factor associated with trials, as this is the evidence included in a Cochrane review; the differences may lie in the translation into practice which might be revealed using process evaluation (Moore *et al.*, 2014). Nutbeam (2002) explained that there had been an increasing awareness of a 'dynamic interrelationship' (p196) between different elements of interventions. Indeed Chamberlain *et al*. (2013), found that the effectiveness of various SS interventions appeared dependent on combining them with other factors.

How might this knowledge on stop smoking interventions be applied in practice?

Influence of HCP role

At different points in the SS pathway NICE PH Guidance (2010) recommends a variety of HCPs take action. Midwives at the booking appointment, SS specialists following referral to the service and other staff as appropriate (NICE, 2010). It has been proposed that the role of the HCP who delivers SS advice is pertinent to the response of the pregnant smoker (McCurry *et al.*, 2002 (GP); Ayadi *et al.*, 2006 (obstetrician); Joseph *et al.*, 2009 (trained non-medic); Song *et al.*, 2015 (specialist advisor)). Therefore, an expert professional, such as a midwife, has been found to be more effective in this regard compared to others, such as family or friends (McLeod *et al.*, 2003; McGowan *et al.*, 2010).

Historically there seems to be considerable variation amongst HCPs as to who perceives this as their responsibility and takes it up (Baxter *et al.*, 2010; Albrecht *et al.*, 2011). An interesting development in the USA is the use of public health nurses in the delivery of SS

advice to pregnant women (Anonymous, 2005). The Smoke Free Mothers and Babies Program is based on the 5As, using an educational model; it primarily sought to take forward the brief intervention offered by obstetricians (Anonymous, 2005). This programme was developed in response to barriers that were experienced when trying to persuade doctors to do more than a brief intervention; it aimed to upskill nurses who were already in place to bridge this gap in care (Anonymous, 2005). One of the SSS models that came into being during the evaluation of babyClear© is using this role, all be it not exactly the same as the American equivalent (Anonymous, 2005). This has not been used in the NE region before and its progress will be eagerly observed. More recently Jaakkola *et al*. (2001) evaluated a population-based initiative, whereby public health nurses in Finland were trained to provide more health education to reduce SiP. However, Jaakkola *et al*. (2001) concluded that education alone was insufficient to increase quit rates, echoing findings from other studies (Chamberlain *et al.*, 2013).

One particular benefit from using a midwife is their broader knowledge about pregnancy, so they can talk to women about all aspects of care, alongside smoking (Bryce *et al.*, 2009). Nevertheless, it also requires a volte-face within the consultation process whereby the HCP, who is usually in the position of advice-giver, has to change their approach to empower the woman to find her own solutions; which might be quite uncomfortable for the midwife (Everett-Murphy *et al.*, 2011).

There are some dissonant voices, including feminists like Deborah Lupton (2012), who would offer a counter-argument. She focuses on redressing the balance of power; identifying the woman as the primary actor and bolstering the view that it is morally and ethically acceptable for her to choose how she treats her body; that she is more than a vessel for the growing baby (Lupton, 2012). She would argue that historically men have conceptualised the woman's body as paradoxically both weak and defective but also dangerous and polluting (Lupton, 2003). That the male-dominated medical profession has medicalised normal, female, reproductive processes - such as childbirth - into illnesses, and through this discourse retained power and control over women's bodies (Lupton, 2003). Women are thus envisaged as baby-carriers rather than individuals in their own right (Lupton, 2003). Sympathy for these arguments is found amongst those who believe in recognising the needs and rights of the mother above other considerations, such as Brook sexual health and wellbeing advisory clinics in the UK (Lupton, 2012; Brook no date).

SS literature concentrates on the negative outcomes for the baby, which will indirectly impact on the mother, but not always on the mother's body directly (Greaves *et al*., 2016). Lupton

(2012) highlights that the mother lives within other social constraints and personal circumstances that may override prioritisation of the baby. This perspective suggests that women may feel that medicalisation insists that freedom of choice is limited, or even taken away (Lupton, 2012). That 'nudging' towards stopping by creating a referral system where the default is to opt-out, and disgust and stigma, are all used as levers to change health behaviours (Blumenthal-Barby & Burroughs, 2012; Lupton, 2014). Lupton (2014) would argue that these are neither ethical nor moral. Lupton (2012) contends that the mother is forced into this position, rather than reaching it willingly; SS interventions, like babyClear©, reject harm reduction and only accept quitting, for example. There is some support in the SS literature for this viewpoint, although it can be perceived by women as either positive or negative (Sloan *et al.*, 2016).

To be more effective in sustaining quits, particularly postpartum, some authors contend that services must become less fetus-centric and focus more on the woman's health (Borlan *et al*., 2013; Greaves *et al*., 2016). Realist and normalisation approaches would support this idea, that it must work for the individual who is expected to change and be appropriate for their context and circumstances, for it to be sustainable (Pawson and Tilley, 1997; Pawson, 2006; May and Finch, 2009).

Discourse

The way in which a SS message is communicated to pregnant smokers has a profound effect on how it is received and, further down the line, whether the woman acts on it or not (Baxter *et al.*, 2010; Sloan *et al.*, 2016). For example, depending on how the CO monitoring was presented in the first instance, influenced women's attitude towards it; when it appeared routine and there was a choice it was received more positively (Sloan *et al.*, 2016). A patient-centred style, similar to an enthusiastic friend, was identified by Everett-Murphy *et al*. (2011) as being the most effective approach. Midwives recognise that asking about smoking is part of their public health role and are well aware that a non-judgemental approach is paramount where public health messages are concerned (Bull, 2007; Lawrence and Haslam, 2007; Bryce *et al.*, 2009; Baxter *et al.*, 2010). Making people feel ashamed or in the wrong encourages them to act defensively, entrench the behaviour and closes their mind to change (Galloway, 2012; Borland *et al.*, 2013). The HCP's language, their attitude towards the smoker, must be full of empathy and understanding, if the woman is going to respond by quitting (Everett-Murphy *et al.*, 2011).

Holism

There is mention of the need to signpost to other agencies, as pregnant smokers often have a multiplicity of needs (NICE, 2010). This has been picked up more robustly in a couple of SS programmes (Bryce *et al.*, 2009; Bailey, 2015). Bryce *et al*. (2009) took a holistic, responsive approach and deliberately sought to deal with the difficult circumstances of women's lives, recognising that smoking behaviour does not exist in a vacuum, it's a coping strategy for life, and offered support and encouragement from this perspective. Similarly, in TIPS they used the basic 5As, but then tailored the programme to meet women's other needs as well (Bailey, 2015). Both studies reported this led to improved outcomes (Bryce *et al.*, 2009; Bailey, 2015).

Health education

Health education has long been widely seen as fundamental to reducing smoking (Kelley, Bond and Abraham, 2001). It can take many forms; for example, advice from HCPs, information by leaflet, text or internet, even a specific workbook (Chamberlain *et al.*, 2013; Bailey, 2015). Educative methods were found to be of little or no effect in this population, however they were more effective when linked with other elements as well (Kelley, Bond and Abraham, 2001; Bullock *et al.*, 2009; Albrecht *et al.*, 2011; Chamberlain *et al.*, 2013).

Making every contact count (MECC)

There is also an expectation that all HCPs who meet the pregnant woman on her health journey will be offering a brief SS intervention (NICE, 2010). This is in line with the UK government's and HCP organisations' drive to maximise the impact, in terms of well-being, on the whole population, and specifically that of pregnant women and future generations, through interactions with all HCPs (PHE, 2016).

Staff training

There is evidence from other studies that sufficient and appropriate staff training is essential (McLeod *et al.*, 2003; Lawrence and Haslam, 2007; Bailey, 2015; University of Ottawa Heart Institute, 2019). NICE PH Guidance recognises the importance of training in providing advice in ways which maximise the desired outcomes (2010). It recommends that all SSS delivery organisations use the standardised training offered by the National Centre for Smoking Cessation and Training (NICE, 2010).

Barriers to effectiveness of stop smoking interventions

The literature suggests that there are many factors that reduce the effectiveness of interventions, from political/societal, to organisational/systems to individual stakeholders (Pawson, 2006). Context at every level changes outcomes (Pawson, 2006; Moore *et al.*, 2014; Squires *et al.*, 2015a; May, Johnson and Finch, 2016). Interventions are introduced into a particular context which will have an impact on its effectiveness (Moore *et al.*, 2014). Some of these factors from the literature are presented below; however, they are explored, using the lens of NPT, within the thesis.

Political and economic elements

Commissioners and providers were found to be under pressure to provide the most effective services for the least cost, as highlighted in the NHS 5-year Forward View and NHS 10-year Plan (2014a; 2019). However, it is necessary to accept that this group of smokers will require considerable time and focused attention, beyond the general smoking population, to follow them up successfully (Parker *et al.*, 2006; McGowan *et al.*, 2010). The way that providers of SS programmes are currently reimbursed does not adequately reward effective, but resource-intensive, methods (Cluss, Levine and Landsittel, 2011). Additionally, they exclude consideration of future savings and may create unintended consequences i.e. favour less-effective interventions (Wanless, 2004; Cluss, Levine and Landsittel, 2011). A model to calculate cost effectiveness of reducing smoking during pregnancy is available; however, the short term costs of implementing an evidence based approach may prevent Trusts taking action (Jones *et al.*, 2018). Also, organisations may want to understand the savings to their organisation rather than overall costs and will be looking at short as well as long term impact (Jones *et al.*, 2018; Wareing, 2018b).

Changing societal norms

One consideration is the wider societal norms, in this case regarding smoking behaviour in general, and specifically in pregnancy (Borland *et al.*, 2013). Midwives reported that health promotion messages made pregnant smokers think about quitting before coming to appointments (McLeod *et al.*, 2003). However, Koshy *et al*. (2010) found that the ban on smoking in public places (DH, 2006) changed public, but not private, smoking habits. A recent review funded by NIHR, reporting in March 2016, found that although the public ban had improved coronary heart disease outcomes, the same was unclear for perinatal deaths (2016). This finding potentially supports the contention of Koshy *et al*. (2010) that people were still smoking in the home.

Key system elements

The literature showed that a clear SS pathway for pregnant smokers is crucial, so maternity staff are able to set the woman's foot upon it unequivocally (NICE, 2010). For example, identifying all smokers accurately (biochemical measure), early in pregnancy and ensuring high rates of referral using opt-out as the default, have been found to be primary requirements (NICE, 2010); however, they are not embedded in every service and this clarity is not necessarily available to staff (Kelley, Bond and Abraham, 2001; McCurry *et al.*, 2002; Baxter *et al.*, 2010; McGowan *et al.*, 2010; Sloan *et al.*, 2016). Even with a clear, evidence-based pathway, it could be hypothesised from the literature that there may be system barriers to increasing quit rates. For example:

- Incomplete implementation of the pathway (Beenstock *et al.*, 2012)
- Inconsistency of the SS message given by different HCPs (Galloway, 2012; Borland *et al.*, 2013)
- Limited recruitment of pregnant smokers into SSS (Parker *et al.*, 2006; Lawrence and Haslam, 2007).

Key staff elements

Further findings from the literature showed that once an effective SS pathway is introduced it is important that staff buy-in to it and its priority is maintained beyond the introductory stages; only then will staff continue to keep it alive in their daily practice (McLeod *et al.*, 2003; Baha and Le Faou, 2009; Bryce *et al.*, 2009; May and Finch, 2009; McGowan *et al.*, 2010). Ways to do this included having a specialist champion, continual refresher training, flexible follow-up systems and well-integrated SS and maternity services (Bull, 2007; Bryce *et al.*, 2009; McGowan *et al.*, 2010; Cluss, Levine and Landsittel, 2011; O'Neill *et al.*, 2015).

Midwives' concerns

The introduction of babyClear© was in the context of midwives concerned that if they brought the challenge to the pregnant woman regarding her smoking, this would damage their relationship and negatively affect the care they could offer (Beenstock *et al.*, 2012). There is some evidence of this concern mirrored in other studies (McLeod *et al.*, 2003; Lawrence and Haslam, 2007; Baxter *et al.*, 2010; Everett-Murphy *et al.*, 2011). However, the converse was found to be the case; pregnant women expected midwives to ask about their smoking habits (McCurry *et al.*, 2002; Aveyard *et al.*, 2005; Lawrence and Haslam, 2007; Baxter *et al.*, 2010). It was discovered that quite unequivocally more intensive advice and support offered by midwives did not increase the perceived stress of the pregnant women, however the staff attitude was crucial (Aveyard *et al.*, 2005; Baxter *et al.*, 2010; Everett-Murphy *et al.*, 2011).

Beenstock *et al.* (2012) also concluded that midwives did not always have confidence in their skills to take the conversation about smoking behaviour forward. This was a widespread finding which points to the requirement for training, equipping and confidence-building of maternity staff in this regard (McLeod *et al.*, 2003; Bull, 2007; Lumley *et al.*, 2009; Baxter *et al.*, 2010). Having a standardised tool which acted as a script was found to be helpful (McLeod *et al.*, 2003). This is closely aligned with having confidence in the effectiveness of the SS interventions; this cannot be assumed (Bull, 2007; Baxter *et al.*, 2010; Everett-Murphy *et al.*, 2011). When midwives are confident and fully engaged with the SS programme, they have been shown to be extremely effective operators and well received by the pregnant women (Bryce *et al.*, 2009).

Midwives and medical staff were also concerned that a more in-depth SS intervention, including biochemical measurement, would take up too much time in clinic appointments (McLeod *et al.*, 2003; Aveyard *et al.*, 2005; Baxter *et al.*, 2010; McGowan *et al.*, 2010). Again, this was a concern highlighted in the preliminary work carried out by Beenstock *et al*. (2012). A recent Cochrane review concluded that, “Trials where the interventions became part of routine pregnancy care did not appear to help more women to quit, which suggests there are challenges to translating this evidence into practice” (Chamberlain *et al.*, 2013, p3). A previous Cochrane review (Lumley *et al.*, 2009) identified the negative staff attitudes as a barrier; they did not think there was time and they were unconvinced about effectiveness of interventions and specialist services. It may be that these fears and concerns create a barrier for midwives in broaching the subject of smoking with pregnant women, in any way that goes beyond a non-challenging enquiry and the offer of information (Baxter *et al.*, 2010; Everett-Murphy *et al.*, 2011). In essence, there is an opportunity cost, no more time is given by employers or commissioners to develop the SS conversation, so in some cases other elements might need to be dropped (Aveyard *et al.*, 2005). This was not considered to be acceptable or sustainable, however other trials have specifically designed the SS intervention to fit within usual care (Naylor, Adams and McNeil, 2002; Aveyard *et al.*, 2005).

Individual factors

The focus of this thesis is not on the pregnant women; however, it remains important to remember who receives the SS intervention. The collection of factors that characterise women who tend to continue to smoke in pregnancy (mentioned above), while not attributable to every pregnant smoker, are signifiers of lives lived in deprived circumstances (McLeod *et al.*, 2003; Joseph *et al.*, 2009; Marmot Review Team, 2010; McGowan *et al.*, 2010; Lewis *et al.*, 2016). As discussed, individual factors have an influence on smokers’ choices and on quitting smoking. Two of the latest avenues of enquiry to support individuals

to quit relate to electronic cigarettes and financial incentives, as discussed (Mantzari, Vogt and Marteau, 2012; Chamberlain *et al.*, 2013; Bauld, Angus and de Andrade, 2014; McConnachie *et al.*, 2017). We know that relapse is more likely if occasional smoking continues (Higgins *et al.*, 2006; McGowan *et al.*, 2010), so addressing individual contexts that promote smoking remains important.

Summary

I have stated the recommendation from NICE (2010), named the foundational theory and provided a brief overview and rationale for the mechanisms and active ingredients that, it is suggested from the literature, are necessary for an effective SS intervention. I have also stated the debate about how they are expected to work, how they do work and their effectiveness. I have written in some detail about the barriers to these intended outcomes, from the published evidence. In particular, I have noted the recent advances in understanding the processes underlying the outcomes and focused on the impact of context at all levels.

Conclusion

Supporting pregnant smokers to change their behaviour through commissioning and providing services is not straightforward. It cannot even be assumed that everyone, from academics, to staff to smokers themselves, believe quitting to be the preferred option. Over-reliance on trials has left a gap. Some elements and active ingredients of interventions have been identified but eliciting mechanisms, synergistic activities and the necessary contexts has largely been overlooked. Expected outcomes and maximum effectiveness have not been realised with improvements still to be made in translating empirical knowledge to the frontline. There have been - and remain - challenges to intervention with continuing questions and room for improvement, especially with regard to effective processes and moderating societal / staff attitudes towards SS interventions.

11.2.2 Additional information about methodologies, methods, MRC guidance and organisational culture and context

Introduction

This appendix presents additional information about methodologies for the process evaluation of complex public health interventions, with specific reference to this thesis. The key points are outlined in Chapter 2.

Theory-based evaluation approaches

Several ways to conduct process evaluation have been emerging; mostly they are methods or frameworks rather than theories like NPT (Moore *et al.*, 2014). Examples include Theory of Change (ToC) (Rogers, 2007), Programme Evaluation (Pawson and Tilley, 2004) and Logic Modelling (W.K. Kellogg Foundation, 2004). They seek to understand the theory that underlies the practice or intervention (Blamey and Mackenzie, 2007). They were developed to meet a need to identify and prioritise key issues that affect the outcomes of an intervention (Moore *et al.*, 2014).

Theory of Change

ToC is one of the main theory-based approaches to evaluation (Rogers, 2007; Brousselle and Buregeya, 2018). The Center for Theory of Change defines it as: “essentially a comprehensive description and illustration of how and why a desired change is expected to happen in a particular context” (ActKnowledge, 2013). It is an example of how thinking has been changing, with ideas traced back to the 1950s (ActKnowledge, 2013). The Aspen Institute, through their work in programme development with communities, developed this idea (ActKnowledge, 2019). Others have referred to understanding what goes on inside ‘the black box’ i.e. what happens to create the change from ‘before’ to ‘after’ the intervention (Michie *et al.*, 2015; Melloni, Pesce and Vasilescu, 2016).

ToC is a tool to assist in making explicit the assumptions about the process between an idea or action and the expected change it will bring about; it articulates short, mid and long-term outcomes (programme theory) and how they will be accomplished (implementation theory) (ActKnowledge, 2013; Clarke *et al.*, 2013). ToC, it has been argued, is more commonly used to explicate the assumptions and less to identify the outcomes (Blamey and Mackenzie, 2007; ActKnowledge, 2013).

The challenge within social programme contexts, to take ToC to its conclusion, may be indicative of the complexities of the context (Blamey and Mackenzie, 2007). Blamey & Mackenzie (2007) postulate that these problems in applying ToC raise the question of its

suitability for purpose and perhaps a publication bias has been created in its favour, if studies that founder at this point are not published. However, the development in thinking represented by ToC has allowed new ideas, theories and methods to evolve to address the challenges of complexity (Brousselle and Buregeya, 2018). These include logic modelling and NPT.

Programme evaluation

Programme evaluation is designed to identify the programme theory i.e. "provide a validated model that will enable a judgment to be made on the intervention", rather than the process of implementation outside the programme (Brousselle and Buregeya, 2018). It pre-dates process evaluation and is an example of how researchers have attempted to meet the challenge of designing studies that answer the questions asked by policy and practice partners using realist approaches (Pawson and Tilley, 2004). The foundations of programme evaluation are in social science, not in the more positivistic sciences (Pawson and Tilley, 2004). The impetus for programme evaluation came from the need to know if the social programmes being rolled out in America in the 1950s, were making any difference to social circumstances (Pawson and Tilley, 2004).

MRC process evaluation guidance (2014)

While the implementation of babyClear© was in progress, the MRC brought out further evaluation guidance: *Process evaluation of complex interventions* (Moore *et al.*, 2014). Building on previous work, which related primarily to RCTs (MRC, 2000) and further guidance published in 2008 (Craig *et al.*), this guidance focused on process evaluation (Moore *et al.*, 2014). The progression from 2000, when the focus for evaluating complex interventions was trial-based work, with a small role for qualitative methods in the preliminary, explorative stages prior to a trial, through to the present acknowledgement of a more significant role for non-experimental methodologies and methods, is discussed in Chapter 2.

The role of other players within the research process was becoming more prominent. For example, funding bodies over recent years have been requiring user involvement as a criterion for allocating money (e.g. Research Councils, SPHR). Indeed, their funder, the UK government, has also been pushing the patient choice agenda and similar democratic, individualising policies (NIHR, 2015). However, the design of RCTs is not conducive to community or user involvement; it comes from a tradition of patient as receiver of treatment, rather than co-worker with the health staff (Rushmer *et al.*, 2015). Prioritising patient and

public involvement therefore, was another reason behind the move away from such biomedical, trial-based research designs, by an organisation like the MRC which, traditionally, did not countenance other methods (Craig *et al.*, 2013).

Before 2014, non-randomised methods were being allowed on occasions when RCTs were understood to be unsuitable (Craig *et al.*, 2013). This was in response to the many changes introduced into healthcare settings today that are not simply asking, is drug A more effective/cost-effective than drug B, but making system or practice changes (Craig *et al.*, 2013). The popularity of qualitative methods was increasing alongside this softening of attitude associated with the hierarchy of research methods (Craig *et al.*, 2013). Their value in complementing trials was being recognised and indeed promoted by Craig *et al.* (2008). Their strength was seen in their ability to explain and explore trial findings, especially in complex contexts (Craig *et al.*, 2008; Moore *et al.*, 2014).

These issues culminated in the guidance, published in 2014 (Moore *et al.*). It is unapologetically in favour of qualitative methods taking a more central role: “High quality evaluation is crucial in allowing policy-makers, practitioners and researchers to identify interventions that are effective, and learn how to improve those that are not … outcome evaluations such as randomised trials and natural experiments are essential in achieving this. But, if conducted in isolation, outcomes evaluations leave many important questions unanswered” (Moore *et al.*, 2014, p9). Most recently, draft guidance for complex interventions, that more fully accepts qualitative methods and both recognises and values their unique contribution is under discussion (Craig *et al.*, 2019).

Stages of evaluation of a complex intervention

MRC guidance (Moore *et al.*, 2014), in its framework for linking the stages of process evaluation (p24) (see Figure 2-2), pulls together the key elements that have emerged over the years.

Key elements of evaluation:

- Logic model - describes the causal assumptions/ theory of change
- Implementation - what is delivered; in what way
- Mechanisms of impact - how does it work
- Outcomes - what happened as a result
- Overarching context - the influences on the outcomes.

There are two stages at which the guidance suggests process evaluation can be used: i) feasibility/pilot phase of the evaluation methods and/or ii) during the implementation of the intervention; however, it recognises that if funding for a process evaluation is not built in at the feasibility stage, it can be difficult to complete it (Moore *et al.*, 2014). The guidance recommends combining the process evaluation with an outcome evaluation to assess effectiveness of the intervention (Moore *et al.*, 2014).

Similarly, when evaluating public health topics, it is important to include methods to understand context and process because of their impact on outcomes (Bryman, 2012). For example, the regional, local and organisational structures and systems that employees work within, impact on their ability to normalise an intervention (May and Finch, 2009). The type of intervention being implemented informs the group process required, therefore a good understanding of the intervention and how it is expected to work is essential in grasping the key elements for the group to carry out the implementation successfully (Moore *et al.*, 2014).

A process evaluation focuses on system and group behaviour change in relation to delivery of a public health intervention, although ultimately it deals with decision-making at an individual level too (see Chapter 2). If we want to support people to change their behaviour, it is important to explore why they behave as they do (Moore *et al.*, 2014; Michie *et al.*, 2015). To answer questions and achieve aims like these, we need to ask participants their views on the systems, the intervention and the reasons for the decisions behind their behaviours (Moore *et al.*, 2014). This leads to a qualitative approach (Bryman, 2012). As promoted by Ogden & Cornwell (2010), rich interview data is most appropriate to unearth the linkages and populate the analytical codes and themes that would explain the process of normalisation of a new intervention.

The most recent research methodologies are beginning to favour a synergistic or cumulative effect of multiple elements over and above the effect of any single element in complex interventions, like some of those in public health (Moore *et al.*, 2014). By 2014, this progression in thinking was reflected in the authorship and the title of the MRC guidance: authors included representation from more centres, especially those with a public health interest, and RCT had been dropped from the title, with process evaluation centre stage, representing a considerable jump forward in terms of accepting the strength of complementary methods (Moore *et al.*, 2014).

Organisational culture and context

Elsewhere it has been noted that, when considering context, the business and organisation literature overlaps with that of complex intervention evaluation and research (Evidence Centre, 2011; Harvey, Jas and Walshe, 2015; Sitton-Kent, 2016). This is because many of the characteristics of 'high reliability organisations' are also apparent within healthcare services (Evidence Centre, 2011; Denison Consulting, 2018). This literature has been drawn on and applied to health organisations, creating its own evidence-base (Greenhalgh *et al.*, 2004; Jacobs *et al.*, 2013; Harvey, Jas and Walshe, 2015).

Jacobs *et al.* (2013) has identified a link between organisational culture and performance. Those organisations with a developmental culture were associated with better performance (Jacobs *et al.*, 2013). An observation that is now being used to improve business cultures (Denison Consulting, 2018). Developmental culture was characterised by being creative, innovative and adaptive, with a risk-taking leader, staff bonded by entrepreneurship and an emphasis on innovation; its valued attributes were: innovation, dynamism, growth and entrepreneurship (Jacobs *et al.*, 2013). Organisations perform better in the areas that were valued within their culture; however external factors can influence and shift the organisational culture e.g. government targets and promotion of market competition (Jacobs *et al.*, 2013). Similarly, The Health Foundation (2011) found that cultures where there was a 'collective mindfulness' that incorporated 'a preoccupation with failure, sensitivity to operations/activities, commitment to resilience, deference to expertise and a reluctance to simplify interpretations of issues or risks' (p7) was more reliable.

A recent example on developing understanding into how organisations react to new knowledge comes from Harvey *et al.* (2015) who employed findings from a review of the evidence by Lane *et al.* (2006) on absorptive capacity. This theory "suggests that contextual factors—both external and internal to the organisation—mediate the way in which the organisation is able to manage and process knowledge" (Harvey, Jas and Walshe, 2015, p49). They applied Lane *et al.* (2006)'s definitions of the elements of absorptive capacity to three NHS organisations and concluded that absorptive capacity was an important component for a learning organisation (Harvey, Jas and Walshe, 2015). Knowing about the culture and context which will produce the best performance and outcomes is the first step, next this knowledge requires translating to those within an organisation (Denison Consulting, 2018).

Summary

This appendix supplements the thesis by giving more detail about choosing an appropriate methodology and method for this doctoral study and expands on advice from MRC guidance (Moore *et al.*, 2014) on how to conduct process evaluations. One other area of research that is discussed is organisational context and culture and its relevance to performance.

11.2.3 Additional notes on justification of method choices

Principles of working ethically

To protect participants' autonomy and promote justice, issues of anonymity and confidentiality need to be approached thoughtfully (Donnan, 2002). In part these are enshrined in law: from 1998 - 2018, which includes the time of data collection and analysis, the Data Protection Act (Great Britain, 1998) controlled how personal information was used and stored by organisations; including the handling of data from study participants by the researchers.

Informed consent ensures that the participant fully understands what they are agreeing to by taking part in the study, with information provided in multiple media, given time to decide, freedom of choice regarding participation and the opportunity to sign in agreement, rather than verbally only, which could be misheard (Donnan, 2002; Ritchie, Spencer and O'Connor, 2003).

Incorporating the views of members of the public, who at some time have used or are likely to use the services under evaluation, promotes ethical research by allowing them to express their views within the research process (NIHR, 2015). This is in line with a democratic society where citizens are involved in publicly funded studies to improve accountability and transparency (NIHR, , 2015). INVOLVE, the public involvement arm of the NIHR, points out that bringing the public into research projects increases study quality and relevance to real life situations (NIHR, 2015).

11.2.4 Timeline of contextual influences

This appendix lists the national, regional and local issues and campaigns that come together to describe the political, legal, media and social context into which babyClear© was implemented during its roll-out across NE England from August 2012 – January 2015.

Campaigns

International, annual initiatives

World Health Organisation, 2014. No Tobacco Day: Strapline in 2014: Raise taxes on tobacco. Initiated by World Health Organisation (2014). Run every May 31st since 1987.

National, annual initiatives

NHS Stoptober: Strapline: 'Because there's only one YOU' (NHS, 2012). Supported by PHE. Run every October since 2012.

NHS No Smoking Day: Strapline in 2014: 'V for victory' (NHS 2014b). Supported by NHS and organised by British Heart Foundation. Run every March since 1984.

Regional initiatives

December 16th 2013. Fresh NE launched a SiP media campaign. Press release about babyClear©, taken up by national, regional and local press, both via newspapers, television and radio (Health News, 2013; ITV (Tyne Tees), 2013; Nelson, 2013; Press Association, 2013). Radio stations that featured reports or interviews included TFM Radio, Real Radio, Capital Radio, Star Radio, Sun FM and Metro Radio.

Fresh NE campaign: Strapline: 'Don't be the 1' (Fresh NE, 2014). Two phases in February/March and August/September 2014, specific to NE, to coincide with implementation of babyClear©.

Feb 12th – March 30th 2014. Included a television advert, radio advert and coverage on BBC Look North. Supported by publicity in the written press and on the two, main local evening news programmes. Not specific to pregnancy, but clear links to family/children as motivation to quit (Fresh NE, 2014).

National context

2003. Payment by Results (PbR) introduced by the government to pay, in part, for NHS services (DH, 2011b).

2007. Smoking banned in public places and work places (DH, 2012; Triggle, 2017).

2008. Commissioning for Quality and Innovation (CQUIN) guidance introduced (NHS England, 2008). Designed to encourage commissioners and providers to support health priorities chosen by the government. Commissioners decide which CQUINs they will adopt, then providers are financially rewarded when they meet the targets. This focuses SSPS delivery on CQUIN targets.

April 2009. Political talk of 'austerity' in response to the financial crisis of 2008 as reported by *Deborah Summers. 26 April. "David Cameron warns of 'new age of austerity'". The Guardian. Archived from the original on 29 April 2009* (Summers, 2009).

October 2009. UK ASH (2009), electronic cigarette briefing, offers a qualified view of their benefits. ASH is a vocal organisation which "was established in 1971 (20 January) by the Royal College of Physicians. It is a campaigning public health charity that works to eliminate the harm caused by tobacco."

June 2010. NICE PH Guidance 26: *Quitting smoking in pregnancy and following childbirth* (2010) published. This has been foundational in promoting stopping smoking in pregnancy.

June 23rd 2010. RCM, express reservations about the introduction of universal, carbon monoxide monitoring. Their "education and research manager Sue Macdonald said: 'There appears to be an emphasis on pregnant women, which is appropriate given the evidence. However, the key issue here for NICE is their emphasis on the CO2 monitor. It is crucial that health practitioners, including midwives, focus on being supportive rather than making women feeling guilty, or as though they may not be truthful. Use of the CO2 monitor has the potential to make women feel guilty and not engaged. We need to look at a range of individualised interventions for women that meet their needs and aspirations.' There is also the cost implication of all midwives carrying monitors, and issues such as safety and infection control, and whether this is the best use of funds to address smoking cessation.'" RCM Midwives: News Views and Analysis, News, Midwives to measure pregnant women's carbon monoxide levels (2010) (No longer available online). NB Error regarding CO2 (it should be carbon monoxide (CO) not carbon dioxide (CO_2).

2010 - 2011. Electronic cigarettes beginning to enter the UK market (Consumer Advocates for Smokefree Alternatives Association (CASAA), 2012-2019).

April - June 2011. Screening of ‘Misbehaving Mums-to-be’, a television programme about babyClear©, featuring Lisa Fendell, one of the main originators of the intervention and trainers during the implementation across NE England (British Broadcasting Corporation, 2011). Seven episodes showed the lives of a series of pregnant women who smoked and their interaction with the babyClear© pathway. (No longer available online).

November 14th 2011. RCM again expresses reservations about antenatal CO testing, and the risk perception intervention element described in this quote: “Antenatal CO testing was highlighted in the recent BBC3 TV programme *Misbehaving mums-to-be.* The baby’s CO reading was displayed on a computer screen and a hard-hitting approach using fetal health as a motivator for quitting was used to promote cessation. Some women found CO feedback in this manner emotionally distressing; not all women successfully stopped. Though reportedly successful in Rotherham …, time will tell whether this high-impact method is effective across the UK” (RCM, 2011).

2011 – 2012. In England, Payment by Results (PbR) included payments towards maternity and SSPS services (DH, 2011b). For SSPS providers this meant being paid for quits achieved, whilst encouraging competition from new market providers. PbR meant that multiple SSPS delivery models began to be seen (Fahy *et al.*, 2014).

March 2012. Health and Social Care Act is passed bringing in a major reorganisation of primary and secondary health and social care (DH, DH, , 2012).

April 10th 2012. Simple guide to the maternity services pathway payment system published by the government**: “…** under the new system, a commissioner will pay a provider for all the pregnancy-related care a woman may need for the duration of her pregnancy, birth and postnatal care (DHSC, 2014). In general, there will be no further payments for individual elements of activity, although there are a small number of clearly identified exceptions. This ‘single payment’ approach contrasts with the current PbR mechanism, where each intervention or hospital attendance triggers additional payments.” (Quote from webpage). Smoking is excluded as an exception but smokers cost trusts more e.g. RCOG recommends extra scans for smokers (RCOG, 2014b).

2012. Paper published by Beenstock *et al.* (2012) What helps and hinders midwives in engaging with pregnant women about stopping smoking? A cross-sectional survey of perceived implementation difficulties among midwives in the NE of England, in

Implementation Science. This was the launch pad for the introduction of babyClear© in the NE.

October 2012. Stoptober media coverage from PHE continues as part of their national campaign mentioned above, although this is not in any way linked directly to pregnancy (NHS, 2012).

2012 – 2013. Electronic cigarettes becoming increasingly popular; safety remains uncertain (CASAA, 2012-2019).

April 2013. Dissolution of Primary Care Trusts (PCTs) comes into force; following a fundamental restructure Clinical Commissioning Groups (CCGs) introduced in the Health and Social Care Act (DH, 2012; NHS, N.d.).
February 2013. RCOG. Guidance no. 31. The Investigation and Management of the Small–for–Gestational–Age Fetus; version 2 published (2013). Supports an SS intervention e.g. CO monitoring to all pregnant smokers. Recommendation: "Interventions to promote smoking cessation may prevent delivery of a small-for-gestational-age infant. The health benefits of smoking cessation indicate that these interventions should be offered to all women who are pregnant and smoke" (RCOG, 2013, p4).

March 13th 2013. No Smoking Day, 30th anniversary of the event. "No Smoking Day works to support smokers who want to quit in a bid to reduce a number of associated health risks and costs. The charity WeQuit does this by raising awareness of the Day, which takes place on the second Wednesday in March every year, and by highlighting the many sources of help available for quitters" (Air Quality News, 2013).

June 2013. Process evaluation data collection started.

June 15th 2013. The Telegraph published an article entitled: Maternity wards closure crisis (Collins, 2013).

June 28th 2013, Challenge Group report, "Smoking Cessation in Pregnancy – A call to action" is published (2013). This report contained many messages similar to babyClear©; that more training and resourcing were required to fully implement NICE PH Guidance (2010), including improved data collection and communication channels (Lowry, Scammell and Challenge Group, 2013).

July 5th 2013. Northern Echo, Births at Bishop Auckland hospital suspended. Ongoing threats to maternity units (Priestley, 2013).

October 2013. Update to PH Guidance 26: *Quitting smoking in pregnancy and following childbirth* (2010) published (NICE, 2013a). No significant changes introduced.

October 2013. Stoptober media coverage continues as part of their national campaign from PHE, although this is not in any way linked directly to pregnancy. Fresh NE supported this with extensive media outputs locally at the time, with headline figures on the number of people from the NE region requesting more information/quit kits on the back of this campaign recorded as 12,100 (Willmore, 2014).

December 30th 2013 – January 31st 2014. PHE national television campaign on smoking (sticky blood/hidden harms message) (2013). Not related to pregnancy, but a highly visible campaign on quitting.

2014 – 2015. Electronic cigarettes becoming increasingly popular; safety remains uncertain (CASAA, 2012-2019).

January 2014. RCOG: Guidance no. 31 – minor revisions (2014b).

March 12th 2014. No Smoking Day. Annual awareness raising event, not specifically in pregnancy (NHS, 2014b).

October 2014. Stoptober media coverage from PHE continues as part of their national campaign mentioned above, although this is not in any way linked directly to pregnancy (NHS, 2012).

December 2014. RCOG: Guidance no. 31 – decided no further revisions required; next review date to be confirmed (2014b).

January 2015. Process evaluation data collection finished.

March 11th 2015. No Smoking Day. Annual awareness raising event, not specifically in pregnancy (NHS,, 2014b).

August 2015 – PHE publish “E-cigarettes: a new foundation for evidence-based policy and practice” (2015a). The long-awaited evidence on the relative safety of e-cigarettes.

October 16th 2015. RCM, in response to the Challenge Group report, took a less negative line on CO monitoring than previously, when Janet Fyle, their Professional Policy advisor said: “The RCM is supportive of pregnant women being offered Carbon Monoxide (CO) Testing at a time when it is appropriate to do so. Depending on the circumstances, it could be at the initial antenatal booking or during subsequent antenatal visits. Women should have the ability to decline testing as with any other area of antenatal screening; CO Testing should be carried out within the context of sufficient time at the antenatal booking and subsequent antenatal appointments, availability of CO monitors and appropriate training for midwives” (2015). (No longer available online).

February 2016. UK ASH, briefing on electronic cigarettes, updated (2016).

March 21st 2016. PHE publish “Saving Babies Lives: Reducing stillbirth and neonatal death: A care bundle”, which has a strong stop smoking message and is in line with NICE recommendations and babyClear© (NHS England, O'Connor and Gould, 2014).

April 28th 2016. “Nicotine without smoke: tobacco harm reduction”, published (RCP,, 2016). It comes down strongly in favour of electronic cigarettes as a means to reduce harm.

February 26th 2017. The Guardian newspaper published an article about promoting the stop smoking agenda in hospitals and among pregnant women (Campbell, 2017). It included the quote from Janet Fyle in 2015 (above) and a reference to our findings published in Bell *et al*. (2018) but did not ascribe them to the team: “The National Institute of Health and Care Excellence (Nice) [sic] already advises hospitals to screen pregnant women to see if they smoke. However, many do not do so, even though recent evidence shows that it helps double the number of women who quit smoking during pregnancy and that those who do go on to have heavier and healthier babies. Smoking in pregnancy increases the risk of stillbirth, babies being small for gestational age, having trouble breathing and other problems” (Campbell, 2017).

September 11th 2017. The Institute for Fiscal Studies publishes research showing the trend towards more maternity unit closures (Kelly and Lee, 2017).

11.2.5 Stop smoking service delivery models

Introduction

Service delivery models (SDMs) for maternity and SSS varied across the region. Broad descriptions of services in each Trust are found in 1.8.4. Listed below is information regarding more specific data, including their senior maternity management attitudes, reported prioritisation of SS, RPT and feedback loop implementation status, follow-up options, data management processes and any specific contextual factors that might be thought to influence the normalisation of the intervention.

SDM 1

Trust A

Senior maternity management attitude – The Head of Midwifery (HoM) was keen to pioneer babyClear© in this Trust. She was a smiling encourager who was seen out and about; her staff talked about her affectionately. She had personally driven babyClear© forward, introducing it enthusiastically and making a way in. Her matron was equally enthusiastic and made time without significant delay to see me, both as part of the scoping exercise when setting up the evaluation, and for an interview after it had been fully implemented for just under a year.

Prioritisation – Trust A, alone among the Trusts, had identified a CQUIN target to promote stop smoking in pregnancy, in line with babyClear© goals. Senior management had reducing SiP as a high priority. The Head of Midwifery (HoM) had appointed a matron with a similar view, who said: “It is valued here”. This attitude cascaded down through her staff. The Trust invested in a key role, an SS specialist with strong data management and leadership skills, who straddled the links between services and had experience of stop smoking in maternity. Her role allowed her to performance manage the maternity and stop smoking staff against the statistics. The maternity staff involved with babyClear© were nominated in 2014 for a Trust award and went on to gain the Chairman’s Award as well.

RPT – Introduced most easily in this Trust. Unusually, there were some midwives in dating scan clinics, even though clinic systems had to be changed and midwives work re-allocated to implement it.

Feedback - Complete feedback loops and performance management of CO monitoring was reported.

Follow-up - MCAs were employed to follow up pregnant women, often with home visits; alternatively, drop-in sessions were offered at a variety of venues with SS advisors. There were some differences in how clinics worked across the area due to different provision, dictated largely by geography e.g. in rural areas they relied on GP surgeries, in towns it was

more drop-ins at community venues such as community centres, libraries. There were some Tier 2 and 3 providers in the community e.g. pharmacies and GP practice nurses, however referrals of pregnant women were sent to specialist advisors at drop-in clinics.

Data management - The data management software, Quit Manager™, was already in use by the SSPS but it required changes, an additional module, to use it for babyClear©. There was a flexible and inclusive attitude to data capture, with examples of adding columns for extra data on non-pregnant family members who were also referred, and those who come to maternity services but were referred on to SSS elsewhere.

Specific context - In July 2013 one of their midwifery-run units was temporarily closed and in April 2014, half of the Trust area seceded from the other, resulting in a different SDM in the separated area. The new structure removed prioritisation of pregnant women and isolated the MCAs from their SS support and pathways into maternity services.

Trust E

Senior maternity management attitude – There was a lack of ownership of the implementation of the intervention by the maternity services in this Trust area, which resulted in a lack of organisation and preparedness.

Prioritisation – Staff were expected to go to the training without really knowing why, they were not given encouragement to see the importance of the work or helped to set up the intervention. The SSP specialist successfully pushed for the re-introduction of stop smoking into the midwives mandatory training, which she gave during the midwives' review meetings.

RPT - Clinic systems had to be changed and midwives re-allocated to make this possible; however, Trust E was one of the earlier implementers as they had midwives carrying out scans who were able to take on the RPT.

Follow-up – In this Trust the SSPS offered face-to-face advice by appointment. This was largely due to its large, geographical area and widely dispersed population. In general, it was not viable to run drop-in clinics. The pregnancy specialist managed and advised all the referrals for pregnant women that entered the service. She made all the calls to the women and followed them up, although occasionally appointments were made for pregnant women with the other advisors in the regular clinics. If the woman was referred and unable to access a clinic the specialist advisor would visit her home.

Feedback – This Trust's paper-based system did not allow for easily accessible feedback, although the specialist advisor kept good records personally and contacted the midwives with any concerns.

Data management - The data was kept on Excel and Access software. There was no intention to introduce Quit Manager™ or a similar software package. There was low

coverage across the region for access to the internet, so it would not have been possible to enter data directly from clinics.

Specific context – This was one of three Trusts/LAs covering one city; one of these neighbouring LAs changed its SDM for SSPS, requiring some support from Trust E as it transitioned. Maternity services at one of their towns was under review and another unit was closed from August 2012 to May 2013, citing a fall in the number of births to 13 in 2011/12, as well as safety incidents. There was an intension to put in place a new structure. Nevertheless, this Trust experienced the least significant system change of all the Trusts during the evaluation period.

Trust H

Senior maternity management attitude – The HoM had experienced long-term sickness during the period of implementation. Once she left, the senior management of the maternity service was restructured.

Prioritisation – There was no midwife with specific responsibility for stop smoking in this Trust and little appetite for the topic to be prioritised.

RPT - Two midwives had been RPT trained, although this was delayed until they had the opportunity to attend as staff shortages meant they could not easily be released for training. It was envisaged that one RPT clinic per week would take place - with patients from the local area only booked into it; however, this will not be enough staff to ensure cover for a regular clinic. It was just becoming operational at the end of the data collection period, over two years after the first implementing Trust had begun offering it.

Follow-up – Local GP surgery or home visits were offered to pregnant women by the SSP specialist. The compactness of the area, and primarily urban population, made home visits less costly in time, and clinics were readily accessible to clients too via public transport. The nurse specialist advisor linked up with the pharmacy if a woman chose to go there, but the SSPS did not direct pregnant women to pharmacies.

Feedback – Feedback loops were still hazy; no pathway was available to establish outcomes. There were many gaps in the loop.

Data management – Quit Manager™ was bought but it had not been implemented, and the data was still on Excel.

Specific context - This Trust was amid turmoil and the SSPS was barely functioning. Some staff hankered after how it used to be and had found the changes very stressful, and indeed the quality of service they could offer suboptimal. At the time of data collection (December 2014) it was under further threat of change.

Trust J

This Trust and LA area were adjacent to Trust H and received their SSPS provision from them until they split away in early 2014. A new SDM was created and established later in 2014; however data is lacking on the details, as it was about to start at the time of interview.

SDM 2

Trusts F and G

Senior maternity management attitude – In Trust G a major, senior management reorganisation was underway with a HoM acting up before a new appointee started in July 2013. In Trust F the HoM remained elusive for the researcher and eventually left. The public health midwife in Trust F reportedly did not have senior management support to implement change. Consequently, there was small sign of driving ahead with babyClear© in either Trust.

Prioritisation – In Trust F the public health midwife's role was new, and her time was split between the Trust and the LA. In Trust G the public health midwife was off long-term, and the role was not backfilled.

RPT – Both Trusts were just beginning to operationalise it at the end of the data collection period, over two years after the first implementing Trust.

Follow-up – All smokers were given the opening times and availability of the nearest or preferred providers. They were rung three times as follow up at one, six and fourteen weeks, to offer support, to record a quit date or attempt to re-engage them with the SSS. The hub offered telephone support calls for as long as the woman chose; this could be for the 12 weeks only or up to delivery if someone preferred. If the AI provider indicated that a woman was lost to follow up, the administrator at the hub would ring them up and try to re-engage them in the SSS. It was entirely up to the woman to contact a provider. The model worked on the principle of easy access to services, however the drop-ins were at set times. There was no home visit provision or extra service for pregnant women from the SSS.

Feedback – There was no appointment system or feedback on women's progress to the SSPS.

Data management – The maternity services used Quit Manager™ to collect data, however the SiP referral system did not communicate with 'Call It Quits', the bespoke referral system for all other smokers in this SDM.

Specific context - The babyClear© package was based on a model that included a specialist service with an appointment system and was not a natural fit for these Trusts. This appears to have discouraged participation in the training due to contract requirements, which identified that AI providers received their training from mentors. The mentors attended but as they were already experienced SS advisors in their own right, but no longer directly

delivering advice and treatment, much of the training was not relevant to them e.g. role plays. The other elements of babyClear© which were different to usual care and were explained as part of the training required adapting to fit a service without specialist provision or appointments, using multiple community providers who were not directly employed by the SS provider. In SDM 2 it was difficult to see how all the providers could advise pregnant women who smoked on a regular and frequent basis, so that advisors would have the opportunity to increase their experience and practice their skills following training. The overarching SSS model incorporated an extra level of mentors, working between maternity services and AI providers. This scenario in Trusts F and G increased the importance of finding a champion who would keep close links and open communication, however from the mentors' point of view the opposite had arisen, with the link between maternity services and the hub mentors not becoming established so far in two out of the three Trusts. Although the mentors felt they had made multiple attempts to communicate into maternity services they did not receive many replies. Issues had not been discussed, solutions not found. This had created significant problems in ensuring a smooth pathway for referred women and around quality of support being offered by these "non-specialist" advisors to pregnant women.

SDM 3

Trust B

Senior maternity management attitude – The HoM was keen to speak to the researcher and had invested in and delegated responsibility for the SS agenda to the public health midwife.

Prioritisation – the public health midwife was well-established. Her primary responsibility was to promote breastfeeding, with broader health promotion also within her remit, including stop smoking.

RPT – the public health midwife was one of three midwives who delivered the RPT at the one site within the Trust; although the other two midwives principally covered it if the public health midwife was unavailable. This Trust succeeded in establishing the RPT relatively early, compared to others.

Follow-up – As in SDM 2, from a preferred provider with extra support from an MCA at their home.

Feedback – There was no appointment system or feedback on women's progress from the SSPS; although the MCAs were able to keep a record.

Data management – As for SDM 2.

Specific context – As for SDM 2, including losing their specialist SSS as babyClear© was first being introduced; however, Trust B differed in that it had an established public health

midwife and MCAs working on the SS agenda as well. The number of assistants was reduced to seven i.e. reduction in those funded by the LA; there have been no other significant system or staff changes during the evaluation period.

SDM 4

Trust D

Senior maternity management attitude – Responsibility for implementing babyClear© was given entirely to the public health midwife who held authority to make changes. With SS as part of her remit she was fully behind anything that improved pregnant smokers' chances of quitting but questioned whether babyClear© was the answer and found herself without a SSPS to refer into.

Prioritisation – the public health midwife put considerable effort into trying to implement babyClear©, including submitting a business case to the board for funding to staff the RPT.

RPT – A major difficulty to implement within existing systems. Like Trust H, Trust D made it available to a sub-group of local smokers only from June 2014.

Follow-up – From November 2013 the SSPS provider was no longer taking on new clients, as part of their exit strategy towards a new provider from April 1st, 2014. So instead of specialist support, pregnant women were referred out to Tier 3 community providers (e.g. pharmacies, GPs, etc.). The referral system broke down, midwives tried to direct women, but this required them to have up to date information on all the Tier 3 pharmacies across the area, so they could signpost to the most appropriate one. Sometimes details changed without the midwives being made aware. This system relied on the woman picking up the opportunity to attend. The SSPS administrator would contact the lady a week later to follow up to check whether she had actually attended and, if she hadn't attended, to try and re-engage her in attending that pharmacy. Major issues around quality of provision between November 2013 and April 2014 were highlighted.

Feedback – No opportunity for feedback. One of the problems had been that the pharmacies did not know who to expect.

Data management – The SSPS relied on an Excel/paper-based system. Along with the change in providers, the LA commissioned Quit Manager™ to go live on 1st April 2014. However, the babyClear© element of Quit Manager™ was not included at this point. By November they were still struggling to complete the payments part of the software implementation and were delaying putting babyClear© data on until this was completed. Therefore, throughout the evaluation data collection period, following the change in provider, it had been a different paper recording system. The administrator tried to follow up and send information back to the public health midwife at the Trust on a regular basis. This data

included whether the women had attended the pharmacy provider that they had been signposted to or not. However, it had been difficult to accurately record and follow up those women who were being signposted to services. Referrals from maternity services to specialist SSS were not kept by maternity.

Specific context – In addition to the regional centre, limited maternity services were available at a local maternity unit, but these were under threat/being downgraded during the time of the evaluation. This hospital had its own SS midwife, but it was unclear if she was being trained in the babyClear© package. The aim for the SSPS was to revert back to the midwives referring the women for treatment and the SSS administrator contacting the woman and booking her in to either the pharmacy or the specialist provider i.e. some pregnancy specialists will also run general drop-in clinics to which pregnant women can go. In addition, the pregnancy SS specialist will pick up some home visits. They are looking for funding for MCAs to carry some of the stop smoking remit.

SDM 5

Trust C

Senior maternity management attitude – The HoM had been in post for a long time and throughout it had pioneered and supported SS in pregnancy. The Trust and SSPS have worked together and formed an integrated care pathway.

Prioritisation – Extra funding had been provided by maternity services to share the cost of SSPS.

RPT – If the pregnant woman was a smoker, she would be channelled into a scan clinic where the RPT was offered by midwives specifically trained in the role and funded 50:50 by maternity and SS services. This Trust established the RPT relatively early.

Follow-up – All pregnant smokers were followed up by the pregnancy advisor and/or MCAs, on referral. They often visited women at home or alternatively invited them to SS clinics, if preferred.

Feedback – This was not systematically available. Maternity data remained within the Trust and due to information governance issues was not shared with the SSPS.

Data management – An Excel/paper-based system was used that made it difficult to provide data. The SS specialist advisor conducted regular audits for performance management.

Specific context - This Trust had implemented NICE PH Guidance (2010) more thoroughly than elsewhere. Changes other than the RPT, that were brought in with babyClear©, were already in place in greater measure than in other Trusts. Therefore, the SS specialist advisor reported that their focus was on improving health outcomes for those pregnant smokers who

were the very least likely to stop smoking. Nevertheless, a member of the CCG was keen to pursue a financial incentives scheme to quit, during the implementation of babyClear©; however, this was postponed.

There have been some staff changes. MCAs have been asked to spend more time in the hospital than formerly, making all care assistant roles the same. Some previously spent all their time in the community but those appointed more recently split their time between the hospital and community. The community midwifery team leads have been reduced from four to two in one area of the Trust. As a result of these changes, potentially staff time will be more stretched, and the SS message downgraded. Resultant on winning the contract to deliver the SSS in Trust D, the SSPS in Trust C became very busy. They took over some of the Trust D SSPS staff and were designing a new SS with a different structure. As part of this, Quit Manager™ had been introduced across both Trusts, and was due to go live in July 2014. A key post, manager of the new service, was taken up by the SS specialist who had excelled in implementing babyClear© and driving the SS agenda forward in Trust A.

11.3 Ethical compliance

11.3.1 Original ethics approval letter

Appendix x: Ethics approval letter for study example

Teesside University
Middlesbrough Tees Valley
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www.tees.ac.uk

Teesside University

PRIVATE AND CONFIDENTIAL

Direct Line: 01642 342750

2nd April 2013

Janet Shucksmith
School of Health & Social Care
Teesside University

Dear Janet

Study No 038/13 - Process evaluation of a complex intervention to promote increased smoking cessation rates among pregnant women in maternity care. Researcher: Susan Jones. Supervisor: Janet Shucksmith, Sharon Hamilton

Decision: Approved with Conditions

Thank you for your application to the School of Health & Social Care Research Governance and Ethics Committee. The Committee reviewed and approved your application on 26th March 2013 and your study may proceed as it was described in your application pack, **on the condition that the comments detailed in the table below are addressed:**

Comment	Applicant Response
General comment: There was no Appendix 2 in the documents submitted for review. It seems that Appendix 9 serves the purpose that is attributed to Appendix 2 in the index page and this opinion is given on that understanding. If that is not correct - i.e. if there is a separate Appendix 2 - this opinion may be invalid and please submit a copy of Appendix 2 for review before commencing the project.	
Conditions	
Section 9a and Protocol: Section 9a states that if there has been an untoward birth outcome the participant will not be contacted for the follow up interview. The corresponding section of the Protocol, however, states that the participants will not be contacted *if the baby has died*. We appreciate this may well be a simple typo in the Protocol but as it concerns one of the main (if not the main) potential ethical issue in this project please follow the process described in Section 9a and not the Protocol.	
Section 11b and Appendix 3: Please also include Prof Shucksmith and Dr Hamilton in those who are informed should any professional malpractice or child protection issues etc emerge.	
Appendix 3, *What would taking part involve?* Section: Please clarify here that the reader is being asked to decide if they give their *personal Consent* to be observed and for data to be recorded about them during the training session. Please explain that the observer has already been given *organisational level permission* (from the project commissioners) to be present and observe the training session - *but* - she will only record data from/about those who have given their *personal Consent* for that to happen. We feel it is very important that people are aware that the observer has permission to observe the training session and make notes etc, but will only make notes about those who have agreed to that.	

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Teesside University

Appendix 12: This states the interviews will be arranged *at a time and place* that is convenient for the participant. The form, however, states the interviews will either be over the phone or at a clinic. Please amend Appendix 12 to clarify the options that are available to participants. It would seem likely that for some the most convenient place could well be in their own homes (new mothers). If this option is available please clarify that here and (as normal) ensure the researchers involved adhere to TU's Lone Worker Policy (if applicable).
Advisory
Appendices 7, 10, 13 and 15: Please check the information given on how long people have to withdraw; Appendix 10 appears not to state a time limit, Appendix 13 states 2 weeks and Appendices 7 and 15 4 weeks. It would appear this time period should be consistent.

Please note:

Where applicable, your study may only proceed when you have also received written approval from any other ethical committee (e.g. NRES) and operational / management structures relevant (e.g. Local NHS R&D). A copy of this approval letter **must** be attached to applications to any other ethical committee. If applicable please forward to me a copy of the approval letter from NRES before proceeding with the study.

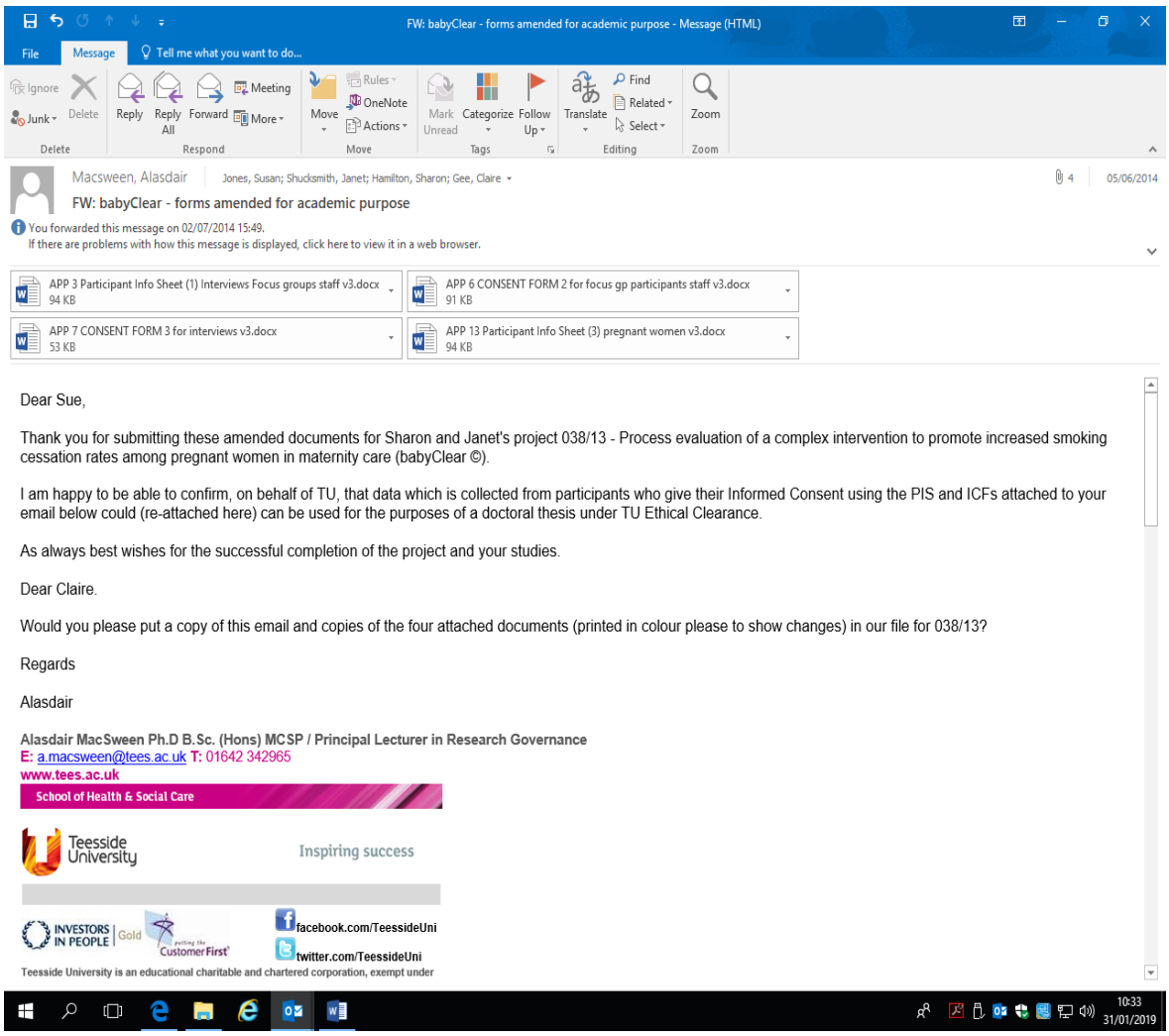
In all cases, should you wish to make any substantial amendment to the protocol detailed, or supporting documentation included, in your approved application pack (other than those required as urgent safety measures) you must obtain written approval for those, from myself and all other relevant bodies, prior to implementing any amendment. Details of any changes made as urgent safety measures must be provided in writing to myself and all other relevant bodies as soon as possible after the relevant event; the study should not continue until written approval for those changes has been obtained from myself and all other relevant bodies.

On behalf of the School of Health & Social Care Research Governance and Ethics Committee please accept my best wishes for success in completing your study.

Yours sincerely

Dr. Alasdair MacSween
Chair
Research Governance and Ethics Committee
School of Health & Social Care

11.3.2 Ethics approval email – for use of data for an academic purpose



FW: babyClear - forms amended for academic purpose - Message (HTML)

File | Message | Tell me what you want to do...

Ignore | Delete | Junk | Reply | Reply All | Forward | Meeting | More | Move | Rules | OneNote | Actions | Mark Unread | Categorize | Follow Up | Translate | Find | Related | Select | Zoom

Delete | Respond | Move | Tags | Editing | Zoom

Macsween, Alasdair Jones, Susan; Shucksmith, Janet; Hamilton, Sharon; Gee, Claire 4 05/06/2014

FW: babyClear - forms amended for academic purpose

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If there are problems with how this message is displayed, click here to view it in a web browser.

APP 3 Participant Info Sheet (1) Interviews Focus groups staff v3.docx 94 KB

APP 6 CONSENT FORM 2 for focus gp participants staff v3.docx 91 KB

APP 7 CONSENT FORM 3 for interviews v3.docx 53 KB

APP 13 Participant Info Sheet (3) pregnant women v3.docx 94 KB

Dear Sue,

Thank you for submitting these amended documents for Sharon and Janet's project 038/13 - Process evaluation of a complex intervention to promote increased smoking cessation rates among pregnant women in maternity care (babyClear ©).

I am happy to be able to confirm, on behalf of TU, that data which is collected from participants who give their Informed Consent using the PIS and ICFs attached to your email below could (re-attached here) can be used for the purposes of a doctoral thesis under TU Ethical Clearance.

As always best wishes for the successful completion of the project and your studies.

Dear Claire.

Would you please put a copy of this email and copies of the four attached documents (printed in colour please to show changes) in our file for 038/13?

Regards

Alasdair

Alasdair MacSween Ph.D B.Sc. (Hons) MCSP / Principal Lecturer in Research Governance
E: a.macsween@tees.ac.uk **T:** 01642 342965
www.tees.ac.uk
School of Health & Social Care

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11.3.3 Participant information sheets

Code Number

PARTICIPANT INFORMATION SHEET

Interviews/focus groups with attendees at training sessions / service managers / trainers

A process evaluation of a complex intervention to promote increased smoking cessation rates among pregnant women in maternity care

Evaluators: Professor Janet Shucksmith, Dr Sharon Hamilton and Susan Jones

We would like to invite you to take part in this evaluation; before you decide please read the following information and discuss it with others if you wish. Please ask us if you have any questions.

What is the purpose of the study?

To evaluate whether a complex, service reconfiguration intervention improves the delivery of smoking cessation interventions to pregnant smokers, whether the reconfigured service can be implemented and sustained effectively, and whether it cost-effectively results in improved pregnancy outcomes.

Why am I being invited to take part?

As someone who is involved in the intervention in some way we would like to hear your views.

What would taking part involve?

We would like to arrange to meet with you at your place of work or a similar location. We will ask you and/or the group what you think about the training, the intervention and its implementation. With your consent, we will record the conversation, which will be typed up and analysed afterwards.

Do I have to take part?

No. Participation is voluntary. Whatever you decide, your employment rights will not be affected. If you are willing to take part in an interview/focus group please complete the reply slip and return it to the evaluator, who will contact you to arrange a time to meet. You will be asked to sign a consent form prior to the interview/focus group commencing.

If you decide that you would like to withdraw your data after you have taken part in an interview please contact us within two weeks and tell us the unique code number written on the top of this sheet and your consent form. We would then destroy the data collected from you and remove you from the study. If you take part in a group discussion you may leave at any time, however please note that it will not be possible to extract your comments from the discussion.

What will happen if I decide to take part?

If you agree to an interview / focus group you will be asked to meet with the evaluator and tell her about your experiences of the training, intervention and implementation either individually or in a

group. These meetings are expected to take between 20 and 60 minutes depending on how much you have to say about the topic. Confidentiality will be maintained by use of the unique code number however an exception to this will be if you reveal any information on professional malpractice or child protection issues or that suggests you might harm yourself or others. The evaluator will discuss this with your line manager and the lead evaluators, Professor Shucksmith and Dr Hamilton.

What are the possible disadvantages or advantages and benefits of taking part?

We don't think there are any disadvantages or advantages for you; however it will give you the opportunity to add your voice to the evaluation of this intervention in your area. There are no incentives or rewards for taking part.

What will happen to the information collected from me?

Your information will be stored securely by Teesside University for 10 years and then destroyed in accordance with the Data Protection Acts (1984, 1998). Access to the study materials and data, while the study is underway, will be restricted to members of the evaluation team. Any audio recording and/or transcript of your interview, any notes taken and/or any paper based materials you may give us will be stored in a locked filing cabinet at Teesside University for the length of the project, and/or stored electronically on a password protected computer at Teesside University. Your data will not have your name on it but will be linked to you by a unique code number which will be stored separately from your data. Identifying references will be removed as far as possible but your anonymity cannot be guaranteed. All findings will be reported anonymously. Some quotes from what you have said might be used in the final report.

Who has approved this study?

This project was approved by the School of Health & Social Care Research Governance and Ethics Committee and the Research and Governance departments at: [Name of Foundation Trust].

Who is organising and funding this study?

It is funded by the NIHR School for Public Health Research.

If you are interested in taking part please return the reply slip or contact Susan Jones via email: Susan.Jones@tees.ac.uk or telephone on 01642 342984. She will then contact you to arrange a time to talk to you.

Who can I contact for more information or if I have any concerns?

If you have any further queries or concerns please contact the chief evaluator Dr Sharon Hamilton via email: Sharon.Hamilton@tees.ac.uk or telephone on 01642 342936.

Or if you have any concerns and would prefer to contact someone at Teesside University who knows about the study but is not involved in it, please contact Alasdair MacSween via email: A.Macsween@tees.ac.uk or telephone on 01642 342965. Contact address for all the above: Parkside West Offices, Teesside University, Borough Road, Middlesbrough, TS1 3BA. **Thank you for reading this information sheet and for considering whether or not to take part in the study.** Version 2 Resubmitted 29th April 2013 for Chair's action.

Code Number

PARTICIPANT INFORMATION SHEET

Interview – unique roles

A process evaluation of a complex intervention to promote increased smoking cessation rates among pregnant women in maternity care

Evaluators: Professor Janet Shucksmith, Dr Sharon Hamilton and Susan Jones

We would like to invite you to take part in this evaluation; before you decide please read the following information and discuss it with others if you wish. Please ask us if you have any questions.

What is the purpose of the study?

To evaluate whether a complex, service reconfiguration intervention improves the delivery of smoking cessation interventions to pregnant smokers, whether the reconfigured service can be implemented and sustained effectively, and whether it cost-effectively results in improved pregnancy outcomes.

Why am I being invited to take part?

As someone who is involved in the intervention in some way we would like to hear your views.

What would taking part involve?

We would like you to attend a meeting with the evaluator at your place of work. She will ask you and/or the group what you think about the training, the intervention and its implementation. With your consent, she will record the conversation, which will be typed up and analysed afterwards.

Do I have to take part?

No. Participation is voluntary. Whatever you decide, your employment rights will not be affected. If you indicate on the reply slip that you are happy to take part in an interview/focus group a time to meet with the evaluator will be arranged and you will be asked to sign a consent form prior to the interview / focus group commencing.

If you decide to withdraw please contact us and tell us the unique code number written on the top of this sheet and your consent form. We would then destroy the data collected from you and remove you from the study. If you take part in a group discussion you may leave at any time, however please note that it will not be possible to extract your comments from the discussion.

What will happen if I decide to take part?

You will be asked to meet with the evaluator and tell her about your experiences of the training, intervention and implementation either individually or in a group. These meetings are expected to take between 20 and 60 minutes depending on how much you have to say about the topic. Confidentiality will be maintained by use of the unique code number however an exception to this

will be if you reveal any information on professional malpractice or child protection issues or that suggests you might harm yourself or others. The evaluator will discuss this with your line manager.

What are the possible disadvantages or advantages and benefits of taking part?

We don't think there are any disadvantages or advantages for you; however it will give you the opportunity to add your voice to the evaluation of this intervention in your area. There are no incentives or rewards for taking part.

What will happen to the information collected from me?

Your information will be stored securely by Teesside University for 10 years and then destroyed in accordance with the Data Protection Acts (1984, 1998). Access to the study materials and data, while the study is underway, will be restricted to members of the evaluation team. Any audio recording and/or transcript of your interview, any notes taken and/or any paper based materials you may give us will be stored in a locked filing cabinet at Teesside University for the length of the project, and/or stored electronically on a password protected computer at Teesside University. Your data will not have your name on it but will be linked to you by a unique code number which will be stored separately from your data. We would normally be able to assure you of anonymity; however, as you know, yours is a unique role so anyone reading the reports and who knows who you are may be able to identify you. Please bear this in mind when making a decision about taking part in the research.

Who has approved this study?

This project was approved by the School of Health & Social Care Research Governance and Ethics Committee and the Research and Governance departments at: [Name of Foundation Trust].

Who is organising and funding this study?

It is funded by the NIHR School for Public Health Research.

If you are interested in taking part please return the reply slip or contact Susan Jones at the training event or via email: Susan.Jones@tees.ac.uk or telephone on 01642 342984. She will then contact you to arrange a time to talk to you.

Who can I contact for more information or if I have any concerns?

If you have any further queries or concerns please contact the chief evaluator Dr Sharon Hamilton via email: Sharon.Hamilton@tees.ac.uk or telephone on 01642 342936.

Or if you have any concerns and would prefer to contact someone at Teesside University who knows about the study but is not involved in it, please contact Alasdair MacSween via email: A.Macsween@tees.ac.uk or telephone on 01642 342965.

Contact address for all the above:

Parkside West Offices, Teesside University, Borough Road, Middlesbrough, TS1 3BA.

Thank you for reading this information sheet and for considering whether or not to take part in the study.

Version 2 Resubmitted 29th April 2013 for Chair's action

11.3.4 Consent forms

Code Number

CONSENT FORM
(Interview)

A process evaluation of a complex intervention to promote increased smoking cessation rates among pregnant women in maternity care

Evaluators: Professor Janet Shucksmith, Dr Sharon Hamilton and Susan Jones

Please put your initials in the boxes to indicate your agreement with the corresponding statements.

1. I have read and understood the information sheet dated 29/04/13 for the above study and have had the opportunity to ask questions.	
2. I know that I have the right to withdraw at any time up to two weeks after interview without giving reasons and without any of my rights being affected.	
3. I agree for the discussion to be digitally recorded.	
4. I understand that my data will be kept confidential and stored for up to ten years after the conclusion of the study in a secure storage facility by Teesside University after which it will be confidentially destroyed.	
5. I understand that my data will not have my name in it but will be linked to me by a Unique Code Number which will be stored separately from the data. Identifying references will be removed as far as possible but I understand my anonymity cannot be guaranteed.	
6. I agree that the research team will have access to the data and information collected about me.	
7. I agree to take part in this study.	

---------- ---------- ----------

Name of Participant Date Signature

---------- ---------- ----------

Name of Evaluator Date Signature

Code Number

CONSENT FORM (Focus group)

A process evaluation of a complex intervention to promote increased smoking cessation rates among pregnant women in maternity care

Evaluators: Professor Janet Shucksmith, Dr Sharon Hamilton and Susan Jones

Please put your initials in the boxes to indicate your agreement with the corresponding statements.

1. I have read and understood the information sheet dated 26/03/13 for the above study and have had the opportunity to ask questions.	
2. I know that I have the right to withdraw at any time up until the focus group or leave the room during the discussion without giving reasons and without any of my rights being affected however I understand that my data cannot be extracted later from the group discussion.	
3. I agree for the discussion to be digitally recorded.	
4. I understand that my data will be kept confidential and stored for up to ten years after the conclusion of the study in a secure storage facility by Teesside University after which it will be confidentially destroyed.	
5. I understand that my data will not have my name in it but will be linked to me by a Unique Code Number which will be stored separately from the data.	
6. I agree that the research team will have access to the data and information collected about me.	
7. I agree to take part in this study.	

----------	----------	----------
Name of Participant	Date	Signature
----------	----------	----------
Name of Evaluator	Date	Signature

11.4 Data collection

11.4.1 Aims and objectives of training sessions

Appendix E

Supporting pregnant women to stop smoking *with* babyClear

Carbon Monoxide Monitoring in Pregnancy

Brief training for Midwifery Staff

Aim:

To enable participants to identify and refer pregnant smokers early in pregnancy

Objectives:

This session will provide participants with:

- An understanding of the impact on foetal and child health of smoking in pregnancy.
- A knowledge of the prevalence of smoking in pregnancy and the ambitions to reduce that prevalence.
- The evidence of what works based on the NICE guidance[1]
- An overview of the support available to pregnant smokers.
- The knowledge and confidence to undertake carbon monoxide monitoring for all pregnant women and to refer all smokers using an 'opt out' system.

[1] Quitting Smoking in pregnancy and following childbirth (PH26). NICE public health guidance, June 2010.

Appendix F

Supporting pregnant women to stop smoking with babyClear

©babyClear training for Stop Smoking Administrative Support Staff

Aim:

To enable participants to deliver person centred care and support that empowers and supports pregnant smokers to change their smoking behaviour and sustain the change.

Objectives:

This course will provide participants with the skills to:

- Establish a positive relationship with the pregnant smoker built on trust and agreement.
- Empower the pregnant smoker to make their own decisions about quitting smoking.
- Demonstrate you understand the difficulties associated with quitting smoking during pregnancy.
- Explore the pregnant woman's personal beliefs about her continued smoking, including her internal feelings and any external criticism or environmental pressures she may be experiencing.
- Adopt a non-prescriptive negotiating style that supports the client's desire to change and encourages her to consider all the issues and make positive choices.
- Respond specifically and appropriately to what the pregnant woman says, utilising reflecting listening, open questioning and summarising skills to elicit self- motivational statements.
- Provide confidence building messages to build up the woman's self-esteem.

Method:

The focus of this course will be to increase and enhance the one-to-one communication skills of the participants, through experiential learning, role play, small group discussions, sharing of case studies and team work.

Appendix G

Smoking in Pregnancy Skills Training Course with babyClear

Aims and objectives for 1 day course

Aim

To enable participants to deliver person centred care and support that empowers and supports pregnant smokers to change their smoking behaviour and sustain the change.

Objectives

This course will provide participants with the skills to:

- Establish a positive relationship with the pregnant smoker built on trust and agreement.
- Empower the pregnant smoker to make their own decisions about quitting smoking.
- Demonstrate you understand the difficulties associated with quitting smoking during pregnancy.
- Explore the pregnant woman's personal beliefs about her continued smoking, including her internal feelings and any external criticism or environmental pressures she may be experiencing.
- Adopt a non-prescriptive negotiating style that supports the client's desire to change and encourages her to consider all the issues and make positive choices.
- Respond specifically and appropriately to what the pregnant woman says, utilising reflecting listening, open questioning and summarising skills to elicit self- motivational statements.
- Provide confidence building messages to build up the woman's self-esteem.

Method

The focus of this course will be to increase and enhance the one-to-one communication skills of the participants, through experiential learning, role play, small group discussions, sharing of case studies and team work.

Appendix H

Smoking in Pregnancy Skills Training Course with babyClear

Aims and objectives for 2 day course

Aim

To enable participants to deliver person centred care and support that empowers and supports pregnant smokers to change their smoking behaviour and sustain the change.

Objectives

This course will provide participants with the skills to:

- Establish a positive relationship with the pregnant smoker built on trust and agreement.
- Empower the pregnant smoker to make their own decisions about quitting smoking.
- Demonstrate you understand the difficulties associated with quitting smoking during pregnancy.
- Explore the pregnant woman's personal beliefs about her continued smoking, including her internal feelings and any external criticism or environmental pressures she may be experiencing.
- Adopt a non-prescriptive negotiating style that supports the client's desire to change and encourages her to consider all the issues and make positive choices.
- Respond specifically and appropriately to what the pregnant woman says, utilising reflecting listening, open questioning and summarising skills to elicit self- motivational statements.
- Provide confidence building messages to build up the woman's self-esteem.

Method

The focus of this course will be to increase and enhance the one-to-one communication skills of the participants, through experiential learning, role play, small group discussions, sharing of case studies and team work.

Appendix I

Smoking in Pregnancy Risk Perception Masterclass *with* babyClear

Aims and Objectives

Aim:

To enable participants to support pregnant women who have previously declined offers of help to understand the risks of smoking in pregnancy and change their smoking behaviour.

Objectives:

This course will provide participants with the skills to:

- Understand the issues that prevent women from accessing the service
- Develop a care pathway to facilitate this intervention with pregnant smokers
- Discuss the dangers of smoking in pregnancy with this group of pregnant smokers
- Be confident in delivering a face to face intervention using the new visual aids and software

Method:

The focus of this course will be to increase and enhance the skills of the participants, through experiential learning, small group discussions and sharing knowledge and experience.

11.4.2 Prompts for observations

PROMPTS for observation of training sessions

(2-hour basic training – midwives / midwifery assistants)

COHERENCE

Does the training help the attendees to gain an understanding of the reasons behind the intervention, including its various elements?

Does it explain the relevance to their practice?

COGNITIVE PARTICIPATION

Do the attendees engage with the training?

How do the trainers engage the attendees?

Are the attendees motivated to implement the intervention?

Are there barriers to cognitive participation? E.g. Do the attendees have reservations about the intervention? How do the trainers handle this?

COLLECTIVE ACTION

Is there a sense of collaboration / team working / across boundaries (e.g. across roles, geographical bases) in the session?

Are questions raised about how this will work out in practice? How other staff may be affected? Practical considerations?

REFLEXIVE MONITORING

Are any plans for future reviewing of the intervention discussed?

What are people's reactions to considerations about the long-term sustainability of the changes initiated by the intervention?

Are any reservations expressed?

GENERAL

How closely the training session meets its stated objectives, whether the content is delivered as planned, and the responsiveness of the participants to the training session and material will also be observed.

PROMPTS for observation of training sessions

(Risk Perception Tool training – midwives)

COHERENCE

Does the training help the attendees to gain an understanding of the reasons behind the 'tough love' intervention?

Does it explain the relevance to their practice?

COGNITIVE PARTICIPATION

Do the attendees engage with the training?

How do the trainers engage the attendees?

Are the attendees motivated to implement the intervention?

Are there barriers to cognitive participation? E.g. Do the attendees have reservations about delivering the 'tough love' intervention? How do the trainers handle this?

COLLECTIVE ACTION

Is there a sense of collaboration / team working / across boundaries (e.g. across roles, geographical bases) in the session?

Are questions raised about how this will work out in practice? How other staff may be affected? Practical considerations?

REFLEXIVE MONITORING

Are any plans for future reviewing of the intervention discussed?

What are people's reactions to considerations about the long-term sustainability of the changes initiated by the intervention?

Are any reservations expressed?

GENERAL

How closely the training session meets its stated objectives, whether the content is delivered as planned, and the responsiveness of the participants to the training session and material will also be observed.

Version 1 Submitted to School of Health & Social Care, Research, Governance & Ethics Committee, 26th March 2013.

11.4.3 Topic guides – all roles

TOPIC GUIDE

Focus group – midwives and SSS staff

(2-hour basic and risk perception tool training for midwives and specialised ½ day training for SSS staff)

COHERENCE

What were your thoughts about the intervention before you came to the training?

Prompt: How clear was your sense of the purpose of the intervention beforehand?

How clear was the intervention made to you in the training?

Prompt: When you finished the training was what you had to do clearly defined in your mind?

Do you have any particular comments you would like to make about the training?

COGNITIVE PARTICIPATION

Has everyone joined in when you have taken it back into practice?

Prompt: Do you think everyone has taken it on board as an idea? Do people think it is a good idea?

COLLECTIVE ACTION

How practical has it proved to be in the work environment?

Prompt: Are there times when it is difficult to implement it?

Did it work out the way you expected?

Prompt: How acceptable was the design? Was it possible to keep to the design when you came to deliver the intervention?

For midwives only: Explore the procedures for tackling referrals who did not attend SSS when they return for the 20-week ultrasound appointment; ask midwives about their experience of delivering the 'tough love' message to women who refuse SSS referral.

Using examples given by the group ask if any changes have been introduced to address implementation issues / ways in which they have had to adapt their practice.

REFLEXIVE MONITORING

Are you reviewing the changes in any way?

Prompt: How do you know if the intervention is making any difference?

How do you see it working out in the future?

For midwives only: Prompt: Is it likely to continue as it is? Are people going to struggle to continue to give a brief intervention or come in with the 'tough love' approach for any reason?

Are there any elements of the intervention that you foresee will be readily sustainable?

Are there any elements of the intervention that you foresee will be difficult to sustain?

Are there any developments / changes that you would like to see into the future?

Prompt: Anything that you feel doesn't work well at the moment – how might it be improved?

How do you see the smoking cessation agenda evolving (locally, nationally)?

Prompt: What impact is that likely to have on your practice?

TOPIC GUIDE

Interviews - maternity service managers (adapted version for SSS managers)

COHERENCE

What is the purpose of the intervention?

Do you see any problems with increasing smoking cessation rates among pregnant women?

Did you expect this intervention to address them? If yes, to what extent is it doing so?

COGNITIVE PARTICIPATION

What actions have you taken to enable this intervention?

Prompt: How has it been made possible for midwifery staff to implement the intervention?

COLLECTIVE ACTION

How have midwifery staff responded to the roll out of the intervention?

Has it impacted on any other staff groups? If yes, explore in what way.

REFLEXIVE MONITORING

What measures have been put in place to assess the impact of the intervention and its implementation?

Is there any opportunity for feedback between stakeholders?

TOPIC GUIDE

Interviews – trainers

COHERENCE

What are you hoping to achieve through the training events?

In what way will those achievements be realised?

Prompt: In what ways does the training promote those achievements?

COGNITIVE PARTICIPATION

Do you believe in what you are doing?

Prompt: Why do you consider what you are doing important?

COLLECTIVE ACTION

How successful have the events been in helping staff to put the intervention into practice?

Prompt: Have the events been able to enthuse, engage and motivate staff to change / improve their practice and introduce this development into their work?

REFLEXIVE MONITORING

Have you been effective in your role as trainer?

Prompt: How do you know how effective you have been?

Version 1 Submitted to School of Health & Social Care Research Governance & Ethics Committee, 26th March 2013.

11.4.4 Example of concept-indicator links

Concept-indicator links are the connection between theory and evidence (Rose, 1982). Using as an example, the interview schedule for frontline staff, the theory is derived from the TDF. The evidence that is being sought is identified in the interview questions. By tabulating them the link is made transparent (see Table 11-1).

Table 11-1: Concept-indicator links for frontline staff

	TDF Domain	TDF Interview questions
1	**Knowledge**	Do you feel you have the necessary information to implement the intervention? Do you feel you have the necessary knowledge to implement the intervention? (Prompt: NICE PH Guidance (2010); previous research in Tyne and Wear)
2	**Skills**	After the training did you felt you had the skills to implement the intervention? (Prompt: how, when) How easy do you find implementing the intervention? (Prompt: How difficult)
3	**Social/Professional role and identity**	How does using this intervention feel? Is it in line with your values? Do you feel that it's a part of your professional role to implement this intervention?
4	**Beliefs about capabilities**	What problems have you encountered while implementing the intervention? What would help you in implementing the intervention as described? How capable are you to continue implementing the intervention? How capable do you feel about implementing the intervention?
5	**Optimism**	How confident are you about implementing this intervention despite the difficulties encountered? How optimistic are you about implementing this intervention despite the difficulties encountered?
6	**Beliefs about consequences**	What do you think will happen if you implement the intervention as described? (Prompts: re themselves, pregnant women, health care system, short and long term consequences) What do you think will happen if you do not implement the intervention as described? (cost and consequences) Do benefits of implementing the intervention compensate for the costs of doing it?
7	**Reinforcement**	Are there rewards associated with implementing the intervention? Are there other things you want to do that might be affected by implementing the intervention?
8	**Intentions**	How much do you want to implement the intervention? How much would you like to implement the intervention?
9	**Goals**	What are your goals when implementing the intervention? (Prompts: feel better, fulfil my professional role, control, promote behaviour change and healthy mother and baby)

10	**Memory, attention and decision processes**	How much effort do you spend in engaging in implementing the intervention? (Prompt: actively think about it) How do you remember to implement the intervention? Why might you decide not to implement the intervention? (Prompt: competing tasks/time, side effects) Could you think about an occasion when you did not implement the intervention? If yes, did you not implement the intervention as a conscious choice?
11	**Environmental context and resources**	Do you think you have all the resources needed to implement the intervention? Are there competing tasks (constraints) that prevent you from using the intervention? Do you feel you have the necessary support/help available to use the intervention?
12	**Social influences**	What do others relevant to you think about using the intervention (Prompts: colleagues, superiors …) To what extent does social influence facilitate or hinder using the intervention? (Prompts: colleagues, superiors…) Will you observe others using the intervention as described? (Do you have a role model)?
13	**Emotion**	Is using this intervention affecting your emotions? How? (Prompt: How does it make you feel?) To what extent do emotional factors facilitate or hinder using the intervention?
14	**Behavioural regulation**	What do you need to do (actions needed) to achieve the goal of using the intervention? Are there procedures/activities you do that encourage/facilitate using the intervention? Is this a new behaviour (using the intervention as described) or an existing behaviour that needs to become a habit? How long are the changes likely to take? Can you suggest systems that can be put in place in order to assure maintenance of long-term changes in terms of using the intervention as part of the system (embed as usual care)? What is it about using the intervention that makes your practice more easy/difficult (changing the environment)?

11.4.5 Question schedules

- including different roles and later modifications

QUESTIONS – for individuals/focus group – midwives and SSS staff

(Midwives have received 2-hour basic or risk perception tool training and SSS staff have received specialised ½ day training or admin training)

INTRODUCTION: Role/s

TRAINING

What were your thoughts about the intervention before you came to the training?

Prompt: How clear was your sense of the purpose of the intervention beforehand?

What do you know about the guidelines/research behind babyClear©?

What do you understand by the term 'the intervention'?

(Do they see it holistically, their work as part of a larger whole, or reductively, just their little bit of it).

How clear was the intervention made to you in the training?

Prompt: When you finished the training was what you had to do clearly defined in your mind?

Do you have any particular comments you would like to make about the training?

PRACTICAL IMPLEMENTATION

How easy do you find implementing/delivering babyClear©?

Prompt: How difficult?

Do you feel that it's a part of your professional role to implement this intervention?

For midwives: Prompt: Who does it focus on the mother or the baby? Who do you think you should focus on?

Is babyClear© in line with what you believe about how to work with pregnant women who smoke?

Prompt: personal belief about choice vs damage to fetus; any sense of role conflict?

Have you encountered any problems while implementing/delivering the intervention?

Prompt: Do you have any personal concerns about your capabilities or are they system difficulties that have impeded the implementation?

What would help you to implement babyClear©, as it is explained in the training?
Do you think you will be able to fully implement babyClear© anyway i.e. despite setbacks?
Prompt: How confident are you that it can be done?

COST/BENEFIT
What has happened / changed as a result of introducing babyClear©?
Prompt: for the pregnant women, for their partners/families, for the staff, health care system, short and long term consequences.

What do you see as the costs of implementing babyClear©?
Prompts: Examples of possible costs - opportunity costs associated with resources; threat to relationship between midwife and mother or stop smoking service and mother; additional midwifery and stop smoking service time taken up; introducing another change; mental and emotional effort involved for all concerned.

Have you seen any benefits or rewards following the implementation of babyClear©?
Prompt: Personally (e.g. satisfaction), in your career (e.g. increased skills or knowledge), health system specifically (e.g. reduced number of admissions from smoking related disease) or generally (e.g. positive stop smoking message in public arena).
Prompt: Other family members/partners taking message on board; attending RPT.

What do you think will happen if you do not implement babyClear© as it is explained in the training?
Prompt: Do the benefits of implementing babyClear© compensate for the costs of it?
Prompt: Does it need a midwife to do the RPT?

Are there other things you want to do that might be affected by implementing babyClear©?
Prompt: affected positively e.g. women feel more cared for or negatively e.g. opportunity costs or women stop attending dating scan.

What do you think might happen to babyClear© in the future?
Do you intend to continue to deliver babyClear© in the future?
Prompt: If it is reviewed after a few months what changes would you make?

EFFECTIVE IMPLEMENTATION

What are your goals when implementing babyClear©?

Prompts: feel better, fulfil my professional role, control, promote behaviour change and healthy mother and baby, improve quit rates and increase funding.

What level of priority is delivering babyClear© for you?

How much effort does it take to engage with implementing babyClear©?

Prompt: actively think about it; is it part of your normal practice?

How do you remember to implement babyClear©?

Why may you decide not to implement babyClear©?

Prompt: competing tasks/time, side effects

Could you think about an occasion when you did not implement babyClear©? Could you describe this to me?

Do you adapt it according to the woman's situation? E.g. depressed.

Did you make a conscious choice not to implement babyClear©?

How practical has it proved to be in the work environment?

Prompt: Are there times when it is difficult to implement it?

Prompt: Is it suitably resourced and supported e.g. by management, peers?

Are there competing tasks that stop you implementing/delivering babyClear©?

Have you had the opportunity to watch others delivering babyClear©?

Did it work out the way you expected?

Prompt: How acceptable was the design? Was it possible to keep to the design when you came to deliver the intervention?

Prompt: Does the age of the pregnant woman make any difference?

Prompt: Are there any other ways that information could be given that would help pregnant women understand the relative risk they are taking?

Using examples given by the participant(s) ask if any changes have been introduced to address implementation issues / ways in which they have had to adapt their practice.

Has everyone (colleagues, superiors) joined in when you have taken it back into practice?
Prompt: Do you think everyone has taken it on board as an idea? Do people think it is a good idea?

FEELINGS
How does it make you feel to be placed in this role with pregnant women smokers?
To what extent do emotional factors facilitate or hinder midwives /SSS successfully using babyClear©?
Are you reviewing the changes in any way?
Prompt: How do you know if the intervention is making any difference?

SUSTAINABILITY
How do you see it working out in the future?
For midwives only: Is it likely to continue as it is? Are there elements that you would definitely want to retain? Are people going to struggle to continue to deliver babyClear© e.g. giving a brief intervention or coming in with the 'tough love' approach for any reason?

Are there any elements of the intervention that you foresee will be readily sustainable?

Are there any elements of the intervention that you foresee will be difficult to sustain?

Are there any developments / changes that you would like to see into the future?
Prompt: Anything that you feel doesn't work well at the moment – how might it be improved?
For SSS staff: What do you think about a separate mums' clinic? Buddy system? Support group?

How do you see the smoking cessation agenda evolving (locally, nationally)?
Prompt: What impact is that likely to have on your practice?

Version 1 Submitted to School of Health & Social Care Research Governance & Ethics Committee, 26th March 2013.

Additional questions used in later interviews

(Modified in response to user panel, observations of training and early interviews) - Version 3, 12th Feb 2014.

Practicality of training everyone on one day

Time lapse between training and implementation – is this an issue?

How are the changes associated with babyClear© working? e.g. changes in how they phrase conversations about smoking to reduce opt out etc.

Ask about the setting up of clinics with the RPT - What changes have had to be made? Are staffing levels an issue?

Are you showing the RPT to everybody who is still smoking?

Do you have any concerns about your relationship with the women as a result of the RPT?

Do you see them again in their pregnancy journey?

What are the procedures for tackling referrals - who have not attended the SSS - when they return for their 20-week ultrasound appointment?

Are the midwives / MCAs getting feedback on take-up of services etc?

Are other family members getting involved through babyClear©?

Has the thought of needing Clexane injections, due to increased risk of blood clotting, made any difference to pregnant smokers?

How much are the consultants on board with babyClear©?

Ask about issues specific to their SSS service delivery model.

Are electronic cigarettes making any difference to the service you offer?

QUESTIONS FOR SENIOR MANAGERS

RELATIONSHIP WORK

ENGAGEMENT WITH HELP FROM FRESH AND TRAINERS. How did you engage with Fresh? With trainers? With SSS?

ENGAGEMENT WITH NETWORKS IN TRUST/SSS. How did you let the Trust know about babyClear©? The SSS?

HOW MANAGED/FACILITATED. Ask them to define what they mean by babyClear©. How did you introduce the changes required?

HOW ENCOURAGED TO LEGITIMISE. How did you enthuse and encourage the staff to take it on board?

SENSE MAKING WORK

COMMUNAL SPEC - GETTING THE MESSAGE OUT/CORRECT AGREED STANDARD. How did you disseminate information about the training? Do you agree with the principles of babyClear©? Does everyone agree with them? Does it need a midwife to do the RP tool?

DIFFERENTIATION - IDENTIFYING SPECIFIC REQUIREMENTS OF BABYCLEAR©. How were the specific requirements of introducing and maintaining babyClear© identified?

PERSONAL SPEC - UNDERSTANDING IT FOR YOURSELF. How familiar are you with the various changes babyClear© has brought in to how SS advice and support is given?

INTERNALISATION - HOW IT SITS WITH KNOWN EXPERIENCE. Is babyClear© consistent with how you think stop smoking advice and support should be given to pregnant women? In what ways?

ENACTING WORK

ENSURING RIGHT RESOURCES AVAILABLE. How have you been able to ensure that the right resources are available?

OPERATIONALISING. What were the obstacles to implementing babyClear©? How did you overcome them? Were there aspects that were easy to implement? How did you create opportunities for staff to innovate/find solutions?

RELATING TO ALL WHO ARE REQUIRED TO IMPLEMENT. How do you keep in touch with those who are delivering babyClear©?

ARE ALL SKILLS NEEDED AVAILABLE? How have you been able to ensure that all the necessary skills have been made available to introduce babyClear©? Opportunity costs? Is it a priority for you?

APPRAISAL

COMMUNALLY. Is there a plan to review progress? Has some review already taken place? When? How? Who with? Particular benefits from b/clear; particular challenges?

INDIVIDUALLY. Have you had to change how you work at all as a result of babyClear©?

FLEXIBILITY TO MAKE CHANGES ON REVIEW. What changes do you anticipate might be required? Is there sufficient flexibility to allow them to be made? What would you recommend if this was being rolled out in another region?

HOW TO KEEP BABYCLEAR© UP TO DATE. How do you make sure it is run according to how it was taught? How will you keep everyone to the standard set in training? Disseminate any changes, improvements? Future sustainability?

Version 1, 24th July 2014 (tailored for each Trust and SSS)

QUESTIONS FOR TRAINERS

RELATIONSHIP WORK

ENGAGEMENT WITH OTHER ORGANISATIONS. How did you initially engage with Fresh? With the trusts? SSS?

ENGAGEMENT WITHIN OWN ORGANISATION. How has rolling babyClear© out across a region worked in your organisation?

HOW MANAGED/FACILITATED. How did the relationships with Fresh/trusts/SSS develop?

HOW ENCOURAGED TO LEGITIMISE. How did you enthuse and encourage the staff to take it on board?

SENSE MAKING WORK

COMMUNAL SPEC - GETTING THE MESSAGE OUT/CORRECT AGREED STANDARD. How did you disseminate information about the training? Did/does everyone agree with the principles of babyClear©? E.g. Do people agree it needs a midwife to do the RP tool? That the 'tough love' approach works/ is not too tough? Other issues?

DIFFERENTIATION - IDENTIFYING SPECIFIC REQUIREMENTS OF BABYCLEAR©. What role did you have in identifying the specific requirements of introducing and maintaining babyClear© in each organisation?

PERSONAL SPECIFICATION - UNDERSTANDING IT FOR YOURSELF. How familiar were/are you with the various contexts that babyClear© has to fit into? Were you surprised by the delays in implementation?

INTERNALISATION - HOW IT SITS WITH KNOWN EXPERIENCE. As a result of implementing babyClear© across the NE, have your views of it as an intervention changed? In what ways?

ENACTING WORK

ENSURING RIGHT RESOURCES AVAILABLE. Were you able to ensure that the right resources were available to carry out your role i.e. the introductions to organisations/training? In what ways?

OPERATIONALISING. What were the obstacles to introducing/carrying out training for babyClear©? How did you overcome them? Were there aspects that were easy to complete?

RELATING TO ALL WHO ARE REQUIRED TO IMPLEMENT. How did you keep in touch with those who still required input i.e. negotiation to implement/training?

ARE ALL SKILLS NEEDED AVAILABLE? How were you able to ensure that all the necessary skills were made available to introduce/train across a region? Opportunity costs? Is it a priority for you?

APPRAISAL

COMMUNALLY. Is there a plan to review progress with the implementing organisations/Fresh? Has some review already taken place? When? How? Who with? (Variability across organisations; lack of identification of how requirements would be met; methods of cascading down)

INDIVIDUALLY. Have you had to change how you work/ the training at all as a result of introducing babyClear© across a region?

FLEXIBILITY TO MAKE CHANGES ON REVIEW. What changes do you anticipate might be required if you were to try and introduce it across a region again? Is there sufficient flexibility to allow them to be made?

HOW TO KEEP BABYCLEAR© UP TO DATE. How do you make sure it is run according to how it was taught? How will you enable organisations to keep everyone to the standard set in training? Disseminate any changes, improvements? Future sustainability?

Version 1, 24th July 2014

QUESTIONS for FRESH EMPLOYEE

Role/responsibilities?
What are they?

Origins of implementation
How did FRESH decide to focus on pregnant women who smoke as a group?

How did the decision to introduce babyClear© come about?

Do you feel you had the necessary information to decide on the most effective framework to implement?
Prompt: Why choose babyClear©?

What were your thoughts about the intervention before you came to advocate for the implementation of babyClear©?
Prompt: How clear was your sense of the purpose of the intervention beforehand?

How strongly do staff at FRESH feel about it? Are opinions similar or divided? How do you feel about babyClear©?

To what extent did everyone at FRESH join in when you initially advocated for it?
Prompt: Do you think everyone has taken it on board as an idea? Do people think it is a good idea?

What would you say to someone who said that babyClear© was manipulating women's emotions to make them do what you want, rather than what they want?

Has this been done before by an organisation like FRESH? If yes, are you in touch with them? What was their experience? If no, what other organisations have been instrumental in implementing babyClear© elsewhere?

Aims and goals
Is babyClear© in line with values of FRESH?

Is babyClear© in line with what you believe about how to work with pregnant women who smoke?
Prompt: any concern e.g. with role conflict for yourself or those delivering the intervention.

Do you feel that it's a part of your professional role to facilitate the implementation of this intervention?

Do you believe babyClear© will reduce risk by increasing smoking cessation?
Prompt: How does it work?

What are your goals when implementing babyClear©?
Prompts: keeps me in a job, fulfil my professional role, meets the goals of FRESH, promotes behaviour change and healthy mother and baby.

How well does babyClear© fit with the goals of Trusts, SSS and individual staff (midwives, MCAs and SSS advisors and admin)?

Preparation of staff and organisations prior to implementation
Do you feel the SSS/maternity staff have the necessary knowledge to implement the intervention?
Prompt: NICE PH Guidance; previous research in Tyne and Wear.
How clear was the intervention made to staff during the training?
Prompt: Was the implementation clearly defined for staff?

How well do you feel the training provided the frontline staff with skills to implement the intervention?
Prompt: how, when, who.

Do you have any particular comments you would like to make about the training?
How do different staff groups understand it to work? Do they believe in it? Do they feel comfortable implementing it? Do they think they are putting themselves or their relationship with women at risk?

Do you have any particular comments you would like to make about the preparation for the implementation? E.g. getting all Trusts on board, contacts with HoMs.

Operationalising babyClear©
How much of your work week is taken up thinking about (and implementing) babyClear©?
Prompt: actively think about it.

Has FRESH had the resources it needs (in the office etc) to support the implementation of babyClear©?

Do you think FRESH has provided all the resources/support/help needed to frontline maternity/SSS staff to implement babyClear©?

How easy / difficult have you found the implementation?
Prompt: In what ways?

What problems have you encountered while implementing the intervention?
Prompt: How practical has it proved to be in the work environment?
Prompt: Are there times when it is difficult to implement it?

What is it about babyClear© that makes it easier/ more difficult in certain locations and organisations?
Prompt: changing the environment.

Did the implementation work out the way you expected?
Prompt: How acceptable was the design? Was it possible to keep to the design when staff came to deliver the intervention?

Have some changes arisen from circumstances beyond your control? Examples?

Have you made changes to the implementation? Examples?

Are there competing tasks (constraints) that prevent maternity/SSS staff from fully implementing babyClear©?

What are the costs (financial, staff effort, resource drain) for FRESH in implementing babyClear©?

*Prompt: Do the benefits of implementing babyClear© compensate for the costs of it?*What have you done to maximise the effectiveness of babyClear©?

Are there procedures/things you do that encourage/facilitate using babyClear©?

What would help you (personally) in implementing babyClear© as described?

What do people think about babyClear©?
What do others relevant to you think about using babyClear©?
Prompts: colleagues, superiors, friends/family …

To what extent does social influence facilitate or hinder frontline staff using babyClear©?
Prompts: colleagues, superiors…

Do other health practitioners buy-in to babyClear© and its methods? E.g. GPs, ward midwives, nurses, pharmacists.

Is advocating this intervention affecting your emotions?
Prompt: how does it make you feel to be part of this implementation?

What part do your own emotions play when advocating for babyClear©?

How confident/ optimistic are you about implementing this intervention despite the difficulties encountered?

Is implementing babyClear© within the capabilities of FRESH?

Was there ever a moment when you thought, yes, this is going to work?

Was there ever a moment when you wondered if you had made the wrong decision? Is this going to work?

Working with other organisations
How well has FRESH been able to work with IPiP/TCCC to implement babyClear©?
Prompt: What is the relationship between TCCC/IPiP?

Has FRESH been able to work equally with all the organisations where babyClear© was being implemented? If no, why not – what influenced this? If yes, what made this possible?
What about in Trusts and SSS – how keen are they to implement babyClear©?
Beforehand how clear were you about what implementing the intervention would mean?

Has your view changed? Did it work out the way you expected?

How well has FRESH risen to the challenge of implementing babyClear© across the region?
Prompt: Has it done anything similar before?

How have you found working with maternity services?
Prompt: Do their values and ways of working coincide with yours?

How would you describe your usual relationship with SSS?

How have you found working with SSS services on babyClear©?

How have different staff groups/organisations responded to babyClear©? E.g. midwives, MCAs, senior managers; Trusts, SSS.

To what extent did everyone join in when introducing it into locations in practice settings?

Outcomes
What has happened / changed as a result of introducing babyClear©?

What do you think will happen if you do not implement babyClear© as described?
Prompts: cost and consequences.

How hopeful are you that babyClear© is going to make any difference?
Prompt: Have your hopes changed over time?

Have you seen any benefits? To frontline staff? To you? To FRESH?
Are there any opportunity costs for FRESH?

Are there any sanctions or negative consequences to frontline staff for implementing babyClear©?
Or for FRESH? Or you personally?

Future
What do you need to do now to maximise the effectiveness of babyClear©?

Is this a new behaviour for frontline staff (using babyClear© as described) or an existing behaviour that needs to become a habit?

Do you see signs of it becoming embedded/routine practice?

How long do you envisage it will take to become routine?

Can you suggest systems that can be put in place in order to assure maintenance of long-term changes in terms of using babyClear© as part of the system (usual care)?

Are you reviewing the changes in any way?
Prompt: How do you know if the intervention is making any difference? What about relapse after delivery (especially if motivation was to quit for baby?)

How do you see it working out in the future?
Prompt: Is it likely to continue as it is? Are people going to struggle to continue to give this approach for any reason?

Are there any elements of the intervention that you foresee will be readily sustainable?

Are there any elements of the intervention that you foresee will be difficult to sustain?

Are there any developments / changes that you would like to see into the future?
Prompt: Anything that you feel doesn't work well at the moment – how might it be improved?

How do you see the smoking cessation agenda evolving (locally, nationally)?
Prompt: What impact is that likely to have on babyClear©?

What will FRESH's role be in maintaining babyClear©?
Prompt: Do you foresee any difficulties with this?

Is there anything you would do differently if you did it again?

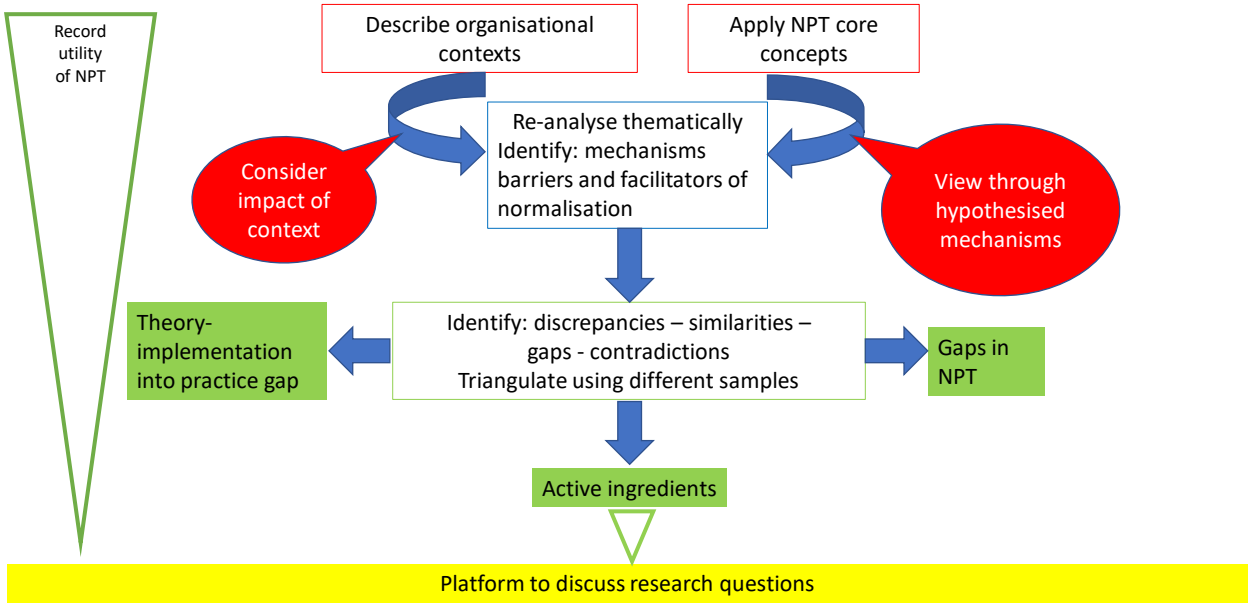
Is there anything more you can do to reduce risk and ensure the success of the implementation?

Version 1, 10th April 2014

11.5 Analysis

11.5.1 Analytical decision tree

Figure 11-2: Analytical decision tree



11.5.2 Example of analysis to derive an active ingredient

Feedback loops

I am taking identifying the contribution of feedback loops as an example of the analytical process. On primary analysis of the interview data, communication and feedback had been viewed as major factors (Jones *et al.*, 2019). These were then written into the logic model.

Logic model

The hypothesis expressed in the logic model (see 6.3) was that by "altering service systems" this "increased communication and integration between maternity and SC services" and this would improve smoking quit rates in pregnancy. The issue of feedback loops, which sits within this procedure as a mechanism to operationalise it, is explained in the extract below from Table 6-5: Hypothesised mechanisms of impact

11 b) How does increased communication / integration between SSS and maternity services increase quit rates?	By establishing robust feedback loops - from the woman's perspective, at each consultation, the HCP (doctor, nurse, midwife, stop smoking advisor) knows what the services have offered, if she has taken it up, her latest smoking status and her attempts to quit (or not) - from the HCPs perspective, they are fully informed as above The results of this - women are then less able to play the system; pull the wool over the eyes of HCPs and know they will be found out if they do - women try to play the system less and so have to face up to the consequences of continued smoking more - HCPs from both services are fully informed and better placed to support women e.g. the patient feels more important and secure if all the information about them is present, the HCP can tailor their advice confidently, therefore the outcomes will improve.

Procedures

Active ingredients, facilitators and barriers were identified along with hypothesised mechanisms from the empirical evidence on procedures (see 7.6).

According to the logic model, the procedure 'increased speed of referral', was dependent on 'altering service systems' to allow the referral system to become quicker, which in turn required high levels of compliance by staff and greater integration between organisations.

During analysis, it was found that many of the procedures, including increased speed of referral, required feedback loops; either in terms of performance management and/or interacting with pregnant smokers.

An example is given below to show how the following NPT codes (see Table 12-3) were used to conduct the analysis and elicit the mechanism.

Table 11-2: Key to NPT concept code abbreviations

C=Coherence	**CA=Collective Action**
Cd=Coherence/differentiation Ccs=Coherence/communal specification Cis=Coherence/individual specification Ci=Coherence/internalisation	CAssw= Collective Action/skill set workability CAci= Collective Action/contextual integration CAiw= Collective Action/interactional workability CAri= Collective Action/relational integration
CP=Cognitive Participation	**RM=Reflexive Monitoring**
CPe= Cognitive Participation/enrolment CPa= Cognitive Participation/activation CPi= Cognitive Participation/initiation CPl= Cognitive Participation/legitimation	RMr= Reflexive Monitoring/reconfiguration RMca= Reflexive Monitoring/communal appraisal RMia= Reflexive Monitoring/individual appraisal RMs= Reflexive Monitoring/systematisation
NI=not included in core concepts	

Procedure: Increased speed of referral

Active ingredients

CAssw, CAci, CAri Systems that allowed early, speedy referrals.

CAci, CAiw, CAri, RMr, RMca, RMia, RMs Organisations that were well integrated and facilitated feedback loops.

Facilitators	*Barriers*
Cd, Ccs, Cis Early referral, prior to booking-in. **CAssw, CAci, CAiw** Some SDMs improved speed / timing of first referral **CPa, CPi, CPl, CAssw, CAiw, CAri, RMr, RMca, RMia, RMs** Efficient feedback loops **Cd, Ccs, CPe, CPa, CAci, CAiw, CAri, RMr, RMca, RMs** Strong communication channels between organisations	**Ccs, Cis, Ci, CPe, CPa, CPi, CPl, CAssw, CAci, CAiw, CAri, RMr, RMca, RMia, RMs** Multiple SSS SDMs created confusion **CPi, CPl, CAci** Some SDMs slowed speed / timing of first referral

Service delivery models (SDMs)

From interviews with designers and trainers of the intervention, and observation of the training sessions, it became clear that there was one model that was seen as the standard from their perspective (see 6.2). In practice however, the data showed that there were five versions of the SDM that were introduced, that all departed from the standard (see 7.4.2). One of the ways that SDMs varied was how they covered the key co-ordinator role. This role, often called a specialist pregnancy advisor, was included in the standard model. This staff member had responsibility for bridging the gap between maternity and SS services. One aspect of this role was to alter the service systems and create robust feedback loops.

Finding

It was found that the specialist pregnancy advisor role was only present in SDMs 1 & 4. The activities that the role was expected to cover were identified as active ingredients, therefore either the role would need to be introduced or alternative ways to operationalise this mechanism, would be required to ensure that feedback loops were established in SDMs 2, 3 & 5.

Significantly, in section 8.7.5, robust feedback systems are raised as an issue regarding sustainability. In the discussion (see 9.4.2), I pick up on how feedback is an important element in normalisation. The findings from the analysis of feedback loops was also used to exemplify the strengths and limitations of using NPT to evaluate the intervention example (see sections 8.6.1 & 8.6.2).

11.5.3 Tables of NPT/NPM core concept definitions from papers

Table 11-3: Definitions of NPM core concepts as defined by the developers/early users

Author, date	Collective Action
(Ehrlich, Kendall and John, 2013) (NPM)	***Interactional workability:*** How the practice was operationalised: the interactional work that professionals and patients do within the clinical encounter and its temporal order. ***Relational Integration:*** The impact on interprofessional relationships: the embeddedness of trust in professional knowledge and practice ***Skill-Set Workability:*** The ''fit'' with existing skillsets: the organisational distribution of work, knowledge and practice across divisions of labour ***Contextual Integration:*** The ''fit'' within the organisational context: its contexts of institutional location and organisational capacity (see May, 2006, p9).
(MacFarlane and O'Reilly-de Brún, 2012) (NPM/NPT)	***Interactional workability*** i.e., how the work is enacted by the people doing it; Is there clarity about appropriate roles and behaviour in the triad of an interpreted consultation? Do all three people believe that the work of the consultation is achievable/achieved? Is the overall impact of the consultation congruent, and is there a sense of meaningfulness about the immediate interaction for all parties involved? ***Relational integration*** i.e., how the work is understood within the networks of people around it; Do all relevant people involved in implementing interpreted consultations trust each other and have confidence in the work that they are there to do as individuals or groups? Do they trust the interpreted consultation as an authentic medical consultation? ***Skill set workability*** i.e., how the work fits with existing divisions of labour; Who needs to do what to streamline the interpreted consultation into routine practice, and are these implementation tasks compatible with these people's existing workload, skills, and professional identity? ***Contextual integration*** i.e., how the work is sponsored or controlled by the organisation in which it is taking place (see May, 2006). What are the formal and informal policies, operating at local and national levels, that might influence implementation? What is the capacity and will of general practices to do the implementation work?
(Atkins *et al.*, 2011) (NPM)	***Interactional workability:*** how does the programme affect interactions between people and practices? ***Relational integration:*** how does the programme relate to existing concepts and relationships? ***Skill-set workability:*** how is the current division of work affected by the programme? **Contextual integration:** how does the programme relate to the organisation in which it is set?

Author, date	Collective Action
(Bouamrane, Osbourne and Mair, 2011) (NPM)	***Interactional Workability:*** it confers an interactional advantage in flexibility accomplishing congruence (i.e. cooperative work) and disposal (i.e. outcomes) of work. ***Relational Integration:*** it equals or improves accountability (i.e. individual working knowledge) and confidence (i.e. understanding of others and of broader intervention) within networks. ***Skill-set workability:*** it is calibrated to an agreed skill-set at a recognisable location in the division of labour. ***Contextual Integration:*** it confers an advantage on an organisation in flexibility executing and realising work.
(Forster *et al.*, 2011) (NPM)	***Interactional workability***: relates to how the work is (or may be) different and how individuals need to work differently in a new model of care – the change required and how this impacts on others both within the service, and those that use the service. E.g. Interactional workability could be identified as a shared understanding of the new role, particularly by those who receive the service. If caseload was to be 'normalised' the women accessing the service would need to perceive this as a model of care that they can access for safe and satisfactory care, with a clear understanding of the role of the caseload midwives. ***Relational integration***: relates to how the work is understood and explores the shared understanding of the change of work allocation within a new model of care, the expertise required for any new roles, and employees' beliefs about who is appropriate to undertake the work. E.g. The construct of relational integration could reflect the peer and professional perceptions of the new model of care. Caseload could become normalised if the care provided by caseload midwives was seen to be safe, and if the caseload midwives were seen to have the skills needed to perform their role, and that they were able to assume the professional responsibilities of their role. ***Skill set workability***: the place of work in the division of labour – explores who is responsible for the work, what skills, knowledge and attributes each contributes, and the agreed operational governance. E.g. Skill set workability is a construct that reflects the organisational division of labour - who should do the work? For caseload to be normalised in the organisation there would need to be a clear articulation of the responsibilities of caseload midwives in relation to other staff, including midwives in standard care and medical staff. ***Contextual integration***: explores how organisational sponsorship and control of work allows the new model to operate within the organisation, including the allocation of resources (May 2006). Contextual integration could be reflected by change within the organisation to ensure the availability of the resources appropriate to provide the model and a place within the organisation for the model to 'fit'. Caseload could become normalised if it were supported by management as a component of cost-effective services offered by the organisation.
(Godden and King, 2011) (NPM)	***Interactional workability:*** how a complex intervention might affect interactions between people and practices ***Relational integration:*** how the intervention relates to existing knowledge and relationships ***Skill-set workability:*** how the intervention affects the current division of labour ***Contextual integration:*** how the intervention relates to the organisation in which it is set.

Author, date	Collective Action
(Gask *et al.*, 2010) (NPM)	***Interactional workability:*** This refers to how work is enacted by the people doing it. A complex intervention will affect co-operative interaction over work (congruence), and the normal pattern of outcomes of this work (disposal). How does collaborative care for depression impact on basic communication, clinical care and treatment at the level of patient and professional? ***Relational integration:*** This refers to how work is understood within the networks of people around it. A complex intervention will affect not only the knowledge required by its users (accountability), but also the ways that they understand the actions of people around them (confidence). How does care for depression impact on the way that health professionals relate to each other? Does it seem to be the right thing to be doing? It is perceived as valid and/or useful? Who needs to be involved in the work? How do we inform them and link with them? ***Skill-set workability:*** This refers to the place of work in a division of labour. A complex intervention will affect the ways that work is defined and distributed (allocation), and the ways in which it is undertaken and evaluated (performance). Does this mean health professionals learning new skills or doing things differently? Is there a person available with the right set of skills to implement care for depression? Does care for depression challenge professional autonomy over working practices? Does it impact on case load and allocation of work? ***Contextual integration:*** This refers to the organisational sponsorship and control of work. A complex intervention will affect the mechanisms that link work to existing structures and procedures (execution), and for allocating and organising resources for them (realisation). Who has the power to make care for depression happen? Does the system want it to happen? How can we divert resources to it?
(James, 2011) (NPM/NPT)	***Interaction Workability:*** an intervention that gets embedded in practice is likely to be one that allows flexible accomplishment of both congruence and disposal. The emphasis is on the flexibility needed for parties to combine their ideas and beliefs (congruence) and make them concrete in outcomes that are meaningful to both parties (disposal). The successfully embedded intervention should reveal evidence of flexible interpersonal work between practitioner and parent. ***Relational Integration:*** the network of relations in which the clinical work is embedded e.g. how the knowledge and practice of the intervention is defined and mediated via accountability and confidence. Accountability refers to internal network and has three components. These are: validity of the knowledge associated with the intervention, which includes ways in which disputes about that knowledge are minimised and the distribution of the knowledge within the hierarchies in the network; expertise, beliefs about the expertise entailed in the intervention; and dispersal, the distribution of knowledge and practice within the network. Confidence refers to the external network and has three components. These are: credibility, the development of a shared understanding of the credibility of the intervention, the ways in which disagreements about the intervention are handled, agreement about how credibility of the intervention should be measured; utility, beliefs about the source of knowledge and about the utility of those sources of knowledge; and expectations about the authority of the dispersion of knowledge in the external network. ***Skill-set workability:*** not considered. ***Contextual integration:*** not considered.

Author, date	Collective Action
(Murray *et al.*, 2011) (NPM)	***Interactional workability:*** refers to the impact that a new technology or practice has on interactions, particularly the interactions between health professionals and patients (consultations). ***Skill set workability:*** refers to the fit between the new technology and the existing skill sets. If a technology requires groups of professionals to work either above or below their current skill set (e.g. it requires a clinician to do clerical work or requires an administrator to make clinical decisions) it is unlikely to normalise. ***Relational integration:*** refers to the impact of the new technology or practice on relations between different groups of professionals. A positive impact on RI is more likely if the technology does not disrupt current lines of responsibility and accountability. ***Contextual integration:*** refers to the fit between the new technology and the overall organisational context. This includes the goals of the organisation, morale, leadership and resources.
(Spangaro, Poulos and Zwi, 2011) (NPM)	***Interactional workability:*** that is, the impact on the worker–patient interaction; ***Relational integration:*** how work is understood by networks of people around it, including patients and other health professionals, and whether it increases accountability or confidence; ***Skill set workability:*** fits with existing role definitions of health professionals; ***Contextual integration:*** the organisational sponsorship and control of the work.
(Murray, May and Mair, 2010) (NPM)	***Interactional workability*:** the degree to which the proposed technology enables (or impedes) interactions between health professionals and patients. ***Relational integration:*** the way in which different professional groups relate to each other and how well the proposed technology fits (integrates) with existing relationships, as well as the degree to which it promotes trust, accountability and responsibility in inter-group relationships. ***Skill set workability:*** the degree to which the e-health initiative fits with existing work practices, skill sets and perceived job role. ***Contextual integration:*** the degree to which the proposed e-health system fits (integrates) with the overall goals and structure of the organisation (context), as well as the capacity of the organisation to undertake the implementation.
(Wilkes and Rubin, 2009) (NPM)	***Interactional workability*:** If open access hysterosalpingography is performed by GPs, will this confer an advantage to patients, GPs and fertility specialists, and do they have a shared belief in the process and goals of open access HSG? ***Relational integration:*** Do GPs, fertility specialists and patients believe that GPs have the necessary expertise to request open access hysterosalpingography, and does it fall within remit of the GP? ***Skill set workability:*** Do general practice, primary care commissioners, NHS guidelines and specialist services agree that the responsibility and skills for arranging hysterosalpingography rest with the GP? ***Contextual integration:*** Does open access hysterosalpingography fit with the practice's way of working, the PCT and the wider NHS and does it confer an advantage on these agencies?

Author, date	Collective Action
(Gask *et al.*, 2008) (NPM)	Within the clinical encounter: ***Interactional workability*** i.e. whether the new working practice is consistent with clinicians and patients sharing assumptions about what clinical work should be done, its legitimacy, its goals, meaning, outcomes and the legitimate forms of conduct and cooperation of each party. For example, the use of digital cameras for on-line dermatological diagnosis only weakly satisfies the interactional workability condition, for that practice focuses the clinician-patient interaction on the camera and a computer-aided protocol rather than on the direct patient-clinician interaction. ***Relational integration*** i.e. whether the new working practice embodies what clinicians personally regard as valid (clinical) knowledge, as appropriate expertise, and the appropriate sources of that expertise; and how far the new working practice conforms to existing public assumptions about what knowledge is credible, useful and authoritative. For example, video-conferenced psychiatric consultations had weak relational integration because they reduced the certainty of interpretation of patients' expressed symptoms and responses. Two conditions which concern the organisational setting: ***Skill-set workability*** i.e. whether the new working practice is compatible with the existing division of clinical labour, methods of monitoring clinical work, allocation of resources and rewards, competence boundaries, degree of clinical autonomy expected for practitioners, and the expected quality of their work. For instance, nurse-led home telecare for people with COPD strongly satisfies this condition because it fits well with specialist nurses' existing activities. ***Contextual integration*** i.e. 'the capacity of … [the host] organisation to understand and agree the allocation of control and infrastructure resources to implementing a complex intervention, and to negotiating its integration into existing patterns of activity'. Remote diagnosis for non-urgent dermatological conditions, for example, only weakly satisfies this condition because it makes the funding, organisation and delivery of specialist clinics more complicated and increases specialists' workloads.

(Elwyn *et al.*, 2008) (NPM)	***Interactional Workability:*** People operationalise a decision support technology when they engage in work that characterised by specific patterns of conduct (congruence), and expectations about their outcomes (disposal). **Congruence** requires shared expectations of the normal conduct and purpose of the clinical encounter; the roles of participants; and the legitimacy of shared decision-making. **Disposal** of participants' problems requires agreement about the meaning and consequences of the shared decision; and expectations of the goals and possible outcomes of the clinical encounter. ***Relational Integration:*** People organise a DST through working to share knowledge and practice (accountability), and beliefs about its value and meaning (confidence). **Accountability** requires agreement about the knowledge and expertise that underpins the shared decision; beliefs about their validity and significance; and agreement about the interpretive contribution of participants. **Confidence** requires agreement about the authority and credibility of the knowledge and expertise through which the shared decision is framed; or beliefs about the utility of this knowledge and the criteria by which it is evaluated. ***Skill-set workability:*** People distribute the work connected to mobilising a decision support technology according to specific formal or informal roles (allocation) and evaluated by reference to shared beliefs about action (performance). **Allocation** requires agreement about the assignment of shared decision-making tasks to participants; beliefs about the ownership and appraisal of the skills; the distribution of resources and rewards; and mechanisms to record participation. **Performance** requires agreement about the content of shared decision-making tasks assigned to participants; shared beliefs about the boundaries of their responsibility; and mechanisms to decide the degree of autonomy available to them.

	Contextual Integration: People enact a DST by working to assign the necessary intellectual property, personnel, and material resources (execution); and to seek to link it to its operational contexts by sustaining the allocation of these resources (realisation). **Execution** is made possible by participants' agreement about distributing responsibility for the conduct of shared decision-making; policies for allocating intellectual and capital resources to participants; and mechanisms for linking participation to organisational structures. **Realisation** is made possible by participants' agreement about the value of shared decision making; policies about the procurement and delivery of personnel and equipment; and mechanisms for modifying organisational objectives.

Author, date	Collective Action
(Mair *et al.*, 2008)(NPM)	***Interactional workability:*** how an e-health system is operationalised by the people using it. ***Relational integration:*** how knowledge and work about an e-health system are mediated and understood within networks. ***Skill-set workability:*** the distribution and conduct of work associated with an e-health system in a division of labour. ***Contextual integration:*** the incorporation of an e-health system within an organisational domain.
(Morriss, 2008) (NPM)	***Interactional workability:*** Shared expectations by professionals between each other and the patient about the nature of the work, including the time taken and its goals. ***Relational integration:*** Credibility of knowledge and practice and the level of expertise that is required ***Skill-set workability:*** Allocation of work within the health service ***Contextual integration:*** Allocation of resources, infrastructure, and control, and integration into existing patterns of activity.

(May *et al.*, 2007b) (NPM)	***Interactional workability:*** This refers to how work is enacted by the people doing it. A complex intervention will affect co-operative interaction over work (congruence), and the normal pattern of outcomes of this work (disposal). Therefore: *a complex intervention is disposed to normalisation if it confers an interactional advantage in flexibly accomplishing congruence and disposal of work*. ***Relational integration:*** This refers to how work is understood within the networks of people around it. A complex intervention will affect not only the knowledge required by its users (accountability), but also the ways that they understand the actions of people around them (confidence). Therefore: *a complex intervention is disposed to normalisation if it equals or improves accountability and confidence within networks*. ***Skill-set workability:*** This refers to the place of work in a division of labour. A complex intervention will affect the ways that work is defined and distributed (allocation), and the ways in which it is undertaken and evaluated (performance). Therefore: *a complex intervention is disposed to normalisation if is calibrated to an agreed skill-set at a recognisable location in the division of labour*. ***Contextual integration:*** This refers to the organisational sponsorship and control of work. A complex intervention will affect the mechanisms that link work to existing structures and procedures (execution), and for allocating and organising resources for them (realisation). Therefore: *a complex intervention is disposed to normalisation if it confers an advantage on an organisation in flexibly executing and realising work*.

Table 11-4: Definitions of NPT core concepts as defined by the developers/understood by users

Author, date	Coherence	Cognitive Participation	Collective Action	Reflexive Monitoring
(Finch *et al.*, 2012)	The process of sense-making and understanding that individuals and organisations have to go through in order to promote or inhibit the routine embedding of a practice to its users. These processes are energised by investments of meaning made by participants.	The process that individuals and organisations have to go through in order to enrol individuals to engage with the new practice. These processes are energised by investments of commitment made by participants.	The work that individuals and organisations have to do to enact the new practice. These processes are energised by investments of effort made by participants.	The informal and formal appraisal of a new practice once it is in use, in order to assess its advantages and disadvantages and which develops users' comprehension of the effects of a practice. These processes are energised by investments in appraisal made by participants.
(Mair *et al.*, 2012)	**Sense-Making Work-** *Differentiation:* Is there a clear understanding of how a new e-health service differs from existing practice? *Communal specification:* Do individuals have a shared understanding of the aims, objectives and expected benefits of the e-health service? *Individual specification:* Do individuals have a clear understanding of their specific tasks and responsibilities in the implementation of an e-health service? *Internalisation:* Do individuals understand the value, benefits & importance of e-health service?	**Relationship Work** *Enrolment:* Do individuals "buy into" the idea of the e-health service? *Activation:* Can individuals sustain involvement? *Initiation:* Are key individuals willing to drive the implementation? *Legitimation:* Do individuals believe it is right for them to be involved?	**Enacting Work** *Skill set workability:* How does the innovation affect roles and responsibilities or training needs? *Contextual integration:* Is there organisational support? *Interactional workability:* Does the e-health service make people's work easier? *Relational integration:* Do individuals have confidence in the new system?	**Appraisal Work** *Reconfiguration:* Do individuals try to alter the new service? *Communal appraisal:* How do groups judge the value of the e-health service? *Individual appraisal:* How do individuals appraise the effects on them and their work environment? *Systematisation:* How are benefits identified or measured?

Table 11-5: Definitions of NPT core concepts as defined by the developers/understood by users (CONTD.)

Author, date	Coherence	Cognitive Participation	Collective Action	Reflexive Monitoring
(Blakeman *et al.*, 2012) (Gallacher *et al.*, 2011)	**Sense-Making Work-investing in making tasks meaningful** *Differentiation:* Defining, dividing up, and categorising task *Communal specification:* making sense of shared versions of tasks *Individual specification:* making sense of personal versions of tasks *Internalisation:* learning how to do tasks in context	**Relationship Work-investing personal and interpersonal commitment to tasks** *Enrolment:* recruiting the self and others to tasks *Activation:* organising a shared contribution to tasks *Initiation*: organising an individual contribution to tasks *Legitimation:* making tasks the right thing to do	**Enacting Work-investing effort and resources in tasks** *Skill set workability:* allocating tasks and performances *Contextual integration*: supporting and resourcing tasks in their social contexts *Interactional workability:* doing tasks, and making outcomes, in practice *Relational integration:* making and communicating reliable knowledge about tasks	**Appraisal Work-investing in comprehending** *Reconfiguration:* changing tasks *Communal appraisal:* shared evaluation of contributions and tasks *Individual appraisal:* individual evaluation of contributions and tasks *Systematisation:* organising a reliable stock of knowledge about tasks
(Bouamrane, Osbourne and Mair, 2011)	**Coherence:** - ways by which agents make sense of a set of practices. - coherence requires that agents collectively invest meaning.	**Cognitive participation:** - means by which participation in a set of practice sis defined and organised. - embedding is shaped by factors which promote or inhibit participation.	**Collective action/operationalisation:** - means by which agents define and organise a set of practices. - embedding is shaped by factors which promote or inhibit the enacting of a set of practices.	**Reflexive monitoring:** forms of appraisal that agents apply to a set of practices. - embedding requires that agents collectively invest in the understanding of a set of practices.
(May *et al.*, 2011b)	Not published.	Not published.	Not published.	Not published.
(May *et al.*, 2011a)	The process of individual and communal sense-making that promote or inhibit the coherence of a complex intervention to its users. These processes are driven by investments of meaning made by participants.	Processes of cognitive participation that promote or inhibit users' enrolment and legitimation of a complex intervention. These processes are driven by investments of commitment made by participants.	Processes of collective action that promote or inhibit the enacting of a complex intervention by its users. These processes are driven by investments of effort made by participants.	Processes of individual and communal reflexive monitoring that promote or inhibit users' comprehension of the effects of a complex intervention. These processes are driven by investments in appraisal made by participants.
(Murray *et al.*, 2010)	Meaning and sense-making by participants.	Commitment and engagement by participants.	The work the participants do to make the intervention function.	Participants reflect on or appraise the intervention.

11.5.4 Deriving NPT concept definitions from the study data

The following steps were repeated for each sub-concept; then they were worked up into defining the core concept.

Step 1: Elements in the first column are based on definitions in published papers; example definitions taken from Mair *et al*. (2012), Blakeman *et al*. (2012) and Gallacher *et al*. (2011) (see Appendix 11.5.3).
Step 2: Items added from the case study data to illustrate each sub-concept in the second column.
Step 3: Looked through and identified the main features that define the concept in terms of the evaluation of babyClear©, using data from the case study, in the third column.
An example of deriving one sub-concept is below.

Table 11-6: Deriving coherence – differentiation

COHERENCE DIFFERENTIATION		
Element of the sub-concept	**Item from the data**	**Summary of main features**
How the new innovation differs from previous practice	Changed the discourse, how women were approached, the focus of the conversation, not a simple addition to practice	Alternative discourse
	Increased awareness amongst staff and patients about smoking cessation	Stop smoking prioritised
	Initial CO reading for all pregnant women New, CO monitors, given to every member of maternity staff, allocated a number CO for smokers at every healthcare visit All pregnant women with a raised CO are referred, not just those who opt-in, at first appointment with maternity services	Introduction of universal, opt-out CO measurement and monitoring
	Changed the name of drop-ins, to avoid implication they are optional	
	Closer working between maternity and SS services	Increase partnership working
	All referrals are contacted by SSS within shorter timeframes and followed up more intensely Re-referral of pregnant smokers; appointments made in their presence immediately For SSS it offered specific training to work with pregnant women Increased follow up by home visit	High intensity SS follow up
	Introduction of RPT; a visual risk tool making the biological effects of smoking clearer Created stop smoking specialist RPT midwives RPT followed by immediate SS follow up afterwards	Introduction of RPT

Table 11-7: Deriving coherence – differentiation (CONTD.)

Element of the sub-concept	Item from the data	Summary of main features
	Data entry onto QuitManager™ Feedback loops in communications between women, SSS and maternity services Increased continuity of care Ability to identify DNA (non-attendance) rates and target professionals involved Allows measure of personal success rate for HCPs Some practice not very different	Systematic feedback loops Some lack of differentiation
Defining, dividing up, and categorising task	All staff offering SS advice given a structured conversation to use with pregnant smokers Midwife to refer in to SSS; opt-out Midwife responsible for their own CO monitor Midwife becomes part of the feedback loop with SSS Midwife to deliver RPT MCAs support midwives in SS role Varied according to SS models but … SSS staff coming in to follow up after RPT, responsibility for home visits Dispute over information governance with regard to patient data collected by SSS Clinicians who enter the data, administration staff who collate/amend the data Checking monitor use, performance management by SS lead (either SSS or NHS depending on SSS model). Training updates to include babyClear© pathway	New discourse – all staff responsible Midwives responsible for SS conversation at book-in and continual CO monitoring throughout pregnancy Maternity & SSS responsible for working in partnership to deliver high intensity follow up and systematic feedback Providing data management system is the responsibility of employing organisations/commissioners Data entry the responsibility of all staff Performance management by SS lead Training updates by SS lead
Clarity of roles	The same roles to be assigned within a variety of SDMs reduced clarity Follow up from RPT may go to a variety of staff depending on SSS model Changing org structures and roles sometimes meant the roles did not exist or lack of staff to do them Administration staff trained to be responsible to set first appointment and encourage women to attend/ be home RPT – designed to stay within maternity	No standardisation across Trusts in terms of which postholders were responsible for which job roles Administrator role expanded to engage women in SS pathway RPT responsibility of midwives

11.5.5 Challenges when applying NPT

Adapting the terminology

Two challenging issues arose in relation to the terminology: the phraseology and the definitions. A secondary issue was the readiness of the terms to interpret the data.

Phraseology

The phraseology of the core and sub concepts can be confusing. Once familiar with the terms their distinctiveness is apparent, nevertheless the words are not in common parlance, especially used together as in the theory (Table 3-6). The way words have been used in seminal and subsequent papers by the originators of NPT has not always been consistent. In addition, the words they have chosen are widely used across the literature in various ways, obscuring the specific meaning in NPT.

The word ‘mechanism’ is an example of multiple usage leading to obfuscation. Within NPT, the core concepts are called generative mechanisms (Table 3-3); also, the way that they work is known as a mechanism (Table 3-1). Although a subtle distinction in meaning between these two uses of the same word, it can be confusing when trying to understand the theory. Elsewhere, Moore *et al.* (2014), in their model of process evaluation, refer to mechanisms of impact (how the delivered intervention produces change) and, synonymously, mechanisms of action; logic modelling refers to delivery mechanisms (how resources will be applied to ensure implementation) and mechanisms of impact (the mechanisms through which an intervention will work) (W.K. Kellogg Foundation, 2004). So, the term ‘mechanism’ is used by May and Finch (2009) to name the concepts and by Moore *et al.* (2014) and W.K. Kellogg Foundation (2004) to describe the means, but all in subtly different ways.

In addition, ‘mechanism’ is used in different ways between papers. May (2006) talks about mechanisms as the **capacity** of an organisation to implement the intervention. In May and Finch (2009) too, it is used at this higher i.e. conceptual, level of abstraction, as stated above, to **describe the nature** of the core concepts. However, in May (2013b) the term ‘mechanism’ is used at a lower i.e. applied level, as the **process** of change, where he brings in a new definition, a “process that brings about or prevents some change in a concrete system” (p3 of 14). The one term, therefore, is expanded to incorporate many shades of meaning. This issue does not only apply to one term.

Another term with at least two meanings is ‘context’, leading to further confusion. It is used to mean the setting and the level (see 3.4, 3.6) without sufficient discrimination. Across the literature it has been used as a non-specific term for variables associated with settings e.g. aspects of physical, political, social and/or economic environments (see 3.4). Initially May (2006) and May and Finch (2009) used ‘context’ quite specifically to mean social systems rather than any other aspect of settings. This is consistent with the sociological origins of NPT (May, 2006).

Similarly, using ‘context’ in relation to levels, it has been recognised that context has three levels, micro, meso and macro, and May and colleagues talk about the importance of including context at each one (see 3.6). As part of extending NPT for wider application, the team have considered the effect of different contexts (May *et al.*, 2011b; May, 2013a; 2013b; May, Johnson and Finch, 2016). In doing so, the authors alter their use of ‘context’ in two ways. In relation to settings, moving away from a purely social perspective, they define context as location (May, 2013a). Secondly, when referring to agents, both individual behaviour change (micro level) and collective action (meso level) are conflated. Phrases, therefore, change their meaning and limit access for a general readership (see 3.7.4 (1)).

Another aspect of phraseology is the standardisation of terms, which is also important, but is sometimes lacking (Walugembe *et al.*, 2019). According to McCleary *et al.* (2013), further exploration of active ingredients has been hampered by this lack, as papers discussing the issue cannot easily be identified. This highlights the importance of the choice of terminology, use of key words and consistency during publication of the development of new theories (McCleary *et al.*, 2013; Walugembe *et al.*, 2019). Future publications, focusing on this aspect of NPT’s utility, may benefit from stating ‘active ingredients’ clearly in the title or abstract to support the development of this piece of evidence (McCleary *et al.*, 2013).

In summary, clearly bounded, standardised terms or phrases are important when communicating new ideas, to ensure that everyone understands them in the same way and they can be found when reviewing the literature. These various ways of using the same words, e.g. mechanism and context, words which are central to the theory and issues of implementation science, detract from the utility of NPT.

Definition of concepts

The definitions of the concepts require translation into common parlance for three reasons. One, for ease of use; two to promote accurate coding; and three, to adapt them to the study as a form of translation of the theory to the data. This was conducted prior to the student

becoming aware of Alverbratt *et al*. (2014), who conduct a similar process; however, it does reinforce that this may be both required and appropriate on occasion. This translation process is two-way i.e. also allowing the data to be understood in terms of the theory through creating applied definitions.

The study specific definitions were devised by tabulating the core and sub concept definitions, firstly from papers authored by the NPT developers and secondly from papers reporting on the application of NPT in other studies, then with some careful consideration definitions were drawn from the case study data (Appendix 11.5.4). By applying the NPT codes, as defined from the data, to the findings about contexts, mechanisms of impact, barriers and facilitators, it was possible to demonstrate how – and to what extent - NPT explained the theory-implementation-practice gap (see 7.7). This was a deductive analysis.

While acknowledging that the interview schedules were based on NPT, so the data would be expected to cover the issues identified by the core concepts and fit the codes relatively easily, this was indeed the case. Using the NPT concepts to create clarity of process, cross-cutting themes were also drawn out inductively, combining data from across the pre-set codes (Jones *et al.*, 2019). These focused on meso/macro level factors that were not specifically identified by NPT core concepts, such as: organisational preparedness, partnerships, management and leadership. This reflected the concerns identified in explaining context (see 9.4.4), suggesting that NPT does not incorporate the effect of the broader context thoroughly enough.

On a micro/meso contextual level, however, the study-specific, core concept definitions were found to offer a way to categorise much of the data from real-life scenarios. They were able to clarify some of the processes implicit in the activities, which were revealed during the implementation, as staff sought to introduce the babyClear© pathway. This was noticeable at every stage, but particularly at the point of collective action. The data showed that staff struggled to identify ways to comply with the babyClear© training in their local organisations and settings. For example: introducing a system by which the clinic clerk is notified that this patient requires an appointment in the scan clinic with the RPT; or wording the verbal invitation to be referred to the SSPS or see the stop smoking advisor in such a way that the women are more likely to agree.

In summary, study-specific definitions were created for greater clarity and to promote accurate coding. This process of translation was conducted systematically and provided workable definitions. On application, they enabled coding to core concepts and also

production of cross-cutting themes, however, these highlighted the limitations of NPT when deducing macro level barriers and facilitators to normalisation.

Overlaps between concepts

When coding, a perception arose that the boundaries of core concepts are unclear and, in some instances, overlap (see 8.6.1 & 8.6.3). In the case of sub concepts, this is even more acute, where the boundaries between them are close by nature, and the data often weaves in between, with aspects of multiple sub-concepts knit together. Sometimes it is not possible to allocate data to separate sub-groups confidently, as the line between them is too fine. Examples of specific areas of overlap were in Coherence, between Individual Specification and Internalisation i.e. the task itself vs the value put upon it. Also, in Collective Action, Contextual Integration and Relational Integration had a slight difference in emphasis but the data were largely too similar to separate.

These difficulties in making coding decisions are reflected in the literature. McEvoy *et al.* (2014), in their review of NPT papers, contest the coding in some of the papers they review and conclude that there are "challenges in applying NPT in terms of managing overlaps between constructs" (p1 of 13). Accepting Franx *et al.* (2012)'s criticism:
"… the application of the NPT constructs to our data has also been problematic due to the overlap and difficulty of discerning the difference between the constructs." (p11 of 13)
More recently, Drew *et al.* (2015) when using eNPT, have continued to find this an issue and added how this complicates coding decisions:

"A challenge in the application of extended Normalisation Process Theory was the overlapping nature of the constructs, meaning that data could be coded into more than one construct ... In addition, we sometimes found it hard to be certain that we were categorising data into the 'correct' construct." They describe the steps they took to overcome coding issues in a systematic way: "A decision was therefore made to code data into more than one construct where relevant ... the study researchers collaborated closely with each other throughout the process to make decisions about how to code the data, to arrive at an agreed code list and application of the list ... There was also the potential for tension between undertaking an abductive approach whilst ensuring the data was not 'forced' into predefined constructs. Coding the data inductively using a thematic analysis before transposing it onto the constructs of extended Normalisation Process Theory helped to address this since we first inductively coded and scrutinised all data for issues relating to implementation before applying extended Normalisation Process Theory." (p6 of 8).

Their decisions are similar to some of those taken in this thesis e.g.
Same data coded into multiple constructs during first analysis
Derived data-driven codes acting like an agreed code list
Thematically analysed to logic model
Inductive coding combined with deductive coding.

Users of May *et al.*'s work have applied it in different ways to address the issue of overlap - sometimes they have stayed with the NPM and primarily used Collective Action, and/or coded to the four core concepts and eschewed using their sub concepts (Murray *et al.*, 2010; Bouamrane, Osbourne and Mair, 2011; Murray *et al.*, 2011; Ehrlich, Kendall and John, 2013). In these studies, NPT is seen as an overarching framework to interpret the findings (Murray *et al.*, 2010; Bouamrane, Osbourne and Mair, 2011; Ehrlich, Kendall and John, 2013; Bouamrane and Mair, 2014a; 2014b; 2014c; Drew *et al.*, 2015). NPT is applied variously to the data, sometimes indirectly, selectively and/or inductively, rather than always directly, completely and deductively (Bouamrane, Osbourne and Mair, 2011; Murray *et al.*, 2011; Ehrlich, Kendall and John, 2013; Bouamrane and Mair, 2014a; 2014b; 2014c; Drew *et al.*, 2015). Rigour and trustworthiness are important methodologically and these are some of the ways that researchers have employed to strengthen their methods when using NPT.

In summary, an issue has been noted regarding the unclear and overlapping boundaries of core and sub concepts, which is confirmed in the literature. This creates challenges when making coding decisions and the potential for loss of systematic analysis. Analytical methods must be devised to overcome boundary uncertainties e.g. create study-specific codes and/or place data in both categories, as in this thesis.

Data outside concepts

During analysis, it was found that the NPT framework does not cover all the data (see 8.6). It felt easy to code data to Coherence/Differentiation that fall outside all other categories because this sub concept characterised what was outside the norm. The main subject that was found to fall outside the NPT concepts when coding was context (see 9.4.4). Both distinguishing the level of collective activity, and incorporating the wider environmental context (e.g. social, political, economic circumstances), are important issues which are largely ignored.

There were other topics also overlooked. In this thesis, one of the active ingredients, the role of champion (see 8.6.1), which was relevant in every concept, had no specific place. Instead, the need for a champion emerged organically as a theme. Another area, which was

similar, in being relevant to all concepts but at home in none, was the emergence and importance of a new discourse (see 8.6.3).

This challenge, that crucial data falls outside the concepts, is supported in the literature (Mair *et al.*, 2008; Gallacher *et al.*, 2011; Mair *et al.*, 2012); however, it is the contention of McEvoy *et al.* (2014) that NPT is not designed or expected to be comprehensive. Indeed, they turn it into a positive attribute:

This is not a problem per se because the NPT, like any middle-range theory, cannot and does not claim to be a theory of everything. This finding indicates that authors are thinking critically about the relevance of NPT constructs to their data and are using it as a heuristic device rather than as a 'conceptual straitjacket.' Such critical and flexible use of NPT is recommended by its developers and advocates of using theory in social science research more generally (McEvoy *et al.*, 2014, p11 of 13).

This argument seems rather disingenuous, as critical thinking is a basic requirement of researchers (e.g. Tierney *et al.*, 2014). In addition, excluding certain topics within the data, from the theory, carries risks with it e.g. aspects of context, it could be argued, are fundamental to normalisation, yet they are not all well integrated (see 9.4.4). This seems potentially dangerous, for example: without situating any discussion arising from analysis within these varieties of contexts, the findings could be misleading or misinterpreted. Alternatively, coders may be tempted to 'force' data into codes inappropriately (Drew *et al.*, 2015).

Conversely, taking excluded data together, it may raise questions about the implementation e.g. are they reflecting further elements of what requires amending or adding, what else is affecting the intervention? Analytical methods must be devised to ensure that NPT does not discriminate against the data. The lack of comprehensiveness seems to have fuelled diversity in applying NPT non-generically; a mix-and-match approach has been taken to analytical methods to maintain trustworthiness.
In summary, it is accepted that NPT is not comprehensive in dealing with the data. This can be both an advantage and disadvantage. It promotes diversity in analysis but risks missing or misinterpreting important findings.

Frequency of use of concepts

The four concepts are not applied equally in terms of frequency and therefore can appear to have differing values. The most evidence exists for Collective Action, as this was the content of the NPM, which was later subsumed into NPT, and has continued to be the preferred concept with the most evidence (see 3.3, 3.4, 3.7.2). There are examples of Coherence taking precedence; Sanders, Foster and Ong (2011) focus on this concept, arguing that their data mapped onto it exclusively. The authors suggested this was due to their population of GPs not finding the intervention coherent, which meant that they did not move beyond the initiation stage (Sanders, Foster and Ong, 2011). This unequal focus given to different concepts has led to gaps in the evidence regarding NPT's utility, with data on sustainability being particularly limited (see 3.7.3; May *et al*. (2018)).

It does appear that the model continues to have currency and the theory has not superseded it (see 3.7.4 (1)). Only when all NPT concepts are used equally is there the potential for equity in understanding its utility. This thesis found that NPT was able to identify the process of implementation, feasibility, fidelity, mechanisms of delivery and impact, and active ingredients but for factors that were likely to influence sustainability, it was unable to make conclusive recommendations due to a lack of equity i.e. less data was available to code to Reflexive Monitoring (see 9.5.1). This is part of the argument behind McEvoy *et al.* (2014)'s conclusion that:

"Whether NPT can serve as a tool to shape implementation processes in ways that will promote integration and embedding of complex interventions remains unclear and merits investigation" (p12 of 13). This is a circular argument, that due to difficulties in implementation because of lack of evidence and knowledge, data is unavailable to inform future sustainability. However, without sustainability how do we know which processes are workable? It is necessary to conceive ways to break out of this conundrum.

In summary, there are both historical and practical reasons for preferring one concept over another during application, but they are not supported theoretically, and novel ways need to be found to address this issue so that questions about sustainability can be answered.

Equity of concepts

There is no sense of weighting one core or sub concept more than another in NPT. This can seem surprising as there are many well-recognised, critical elements to implementation e.g. resources, or lack of them, are 'showstoppers' in project management terms Akker (1996)

(Prince2™ Compact, 1996) i.e. they are on the critical path. Initially coded mostly under Collective Action/Contextual Integration, and a little under Cognitive Participation/Activation, the critical importance of resources is not clear in NPT. An exploration of the complexity of management decisions, supply chains etc. that relate to the provision of resources might have been expected. Their effect on the normalisation of the implementation, and some associated weighting, might be useful. This is just one possible example.

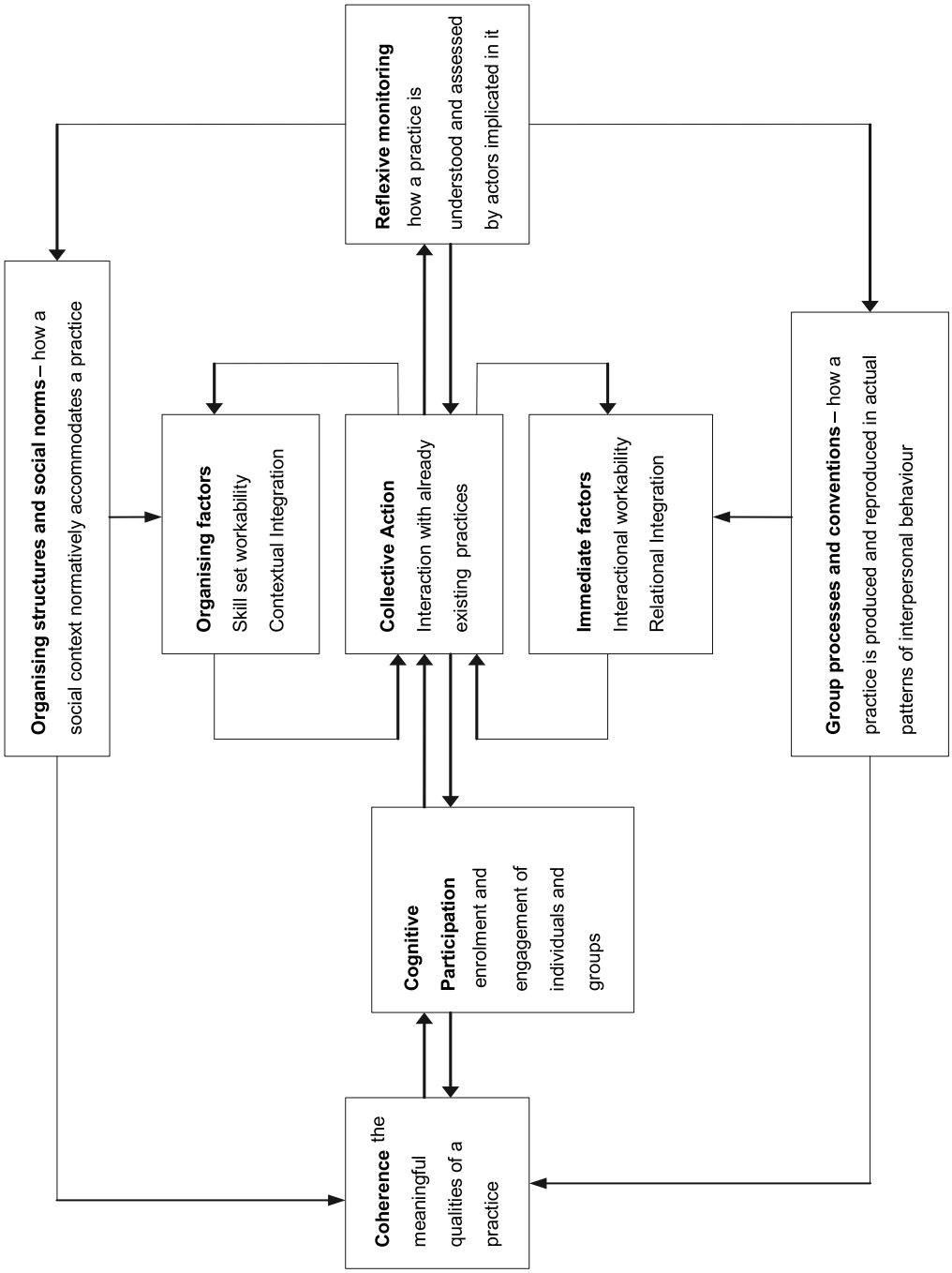
Feedback loops were another important attribute of normalisation. They are revealed by the data to be important for consistent and meaningful monitoring, where they were reported as reinforcing good practice. Data on feedback loops may appear most relevant in Reflexive Monitoring but if they are to reinforce good practice, they are also relevant to each concept i.e. to support Coherence and Cognitive Participation and provide a foundation for Collective Action. Many areas struggled to complete feedback loops and focusing on one core concept, e.g. Collective Action, as many studies do (see 9.5.1; May *et al*. (2018)), would not capture findings on the barriers or benefits of them. Using selected parts of NPT only, as suggested for dealing with NPT's lack of comprehensive cover may have drawbacks. A next step, identified by the developers of NPT, is to explore the relative significance of mechanisms (May *et al.*, 2018).

In summary, there is no weighting on certain core or sub constructs, as might be expected, given the critical importance of particular activities over others. They do not recognise that elements on the critical path can stop the implementation altogether or that the wider, contextual view is always necessary. These issues, when applying NPT, may lead to misinterpretation of data regarding transferability and sustainability of complex interventions.

Linearity and iteration

The findings suggest there is a tension in NPT between linearity and iteration. Linearity is associated with a positivist view (Coote, Allen and Woodhead, 2004) while NPT is set out as an iterative model; there is no start or end point and each core concept is both affecting and affected by each concept, with a focus on Collective Action (May and Finch, 2009).

Figure 11-3: Model of the components of NPT



Taken from May & Finch (2009) Figure 1.

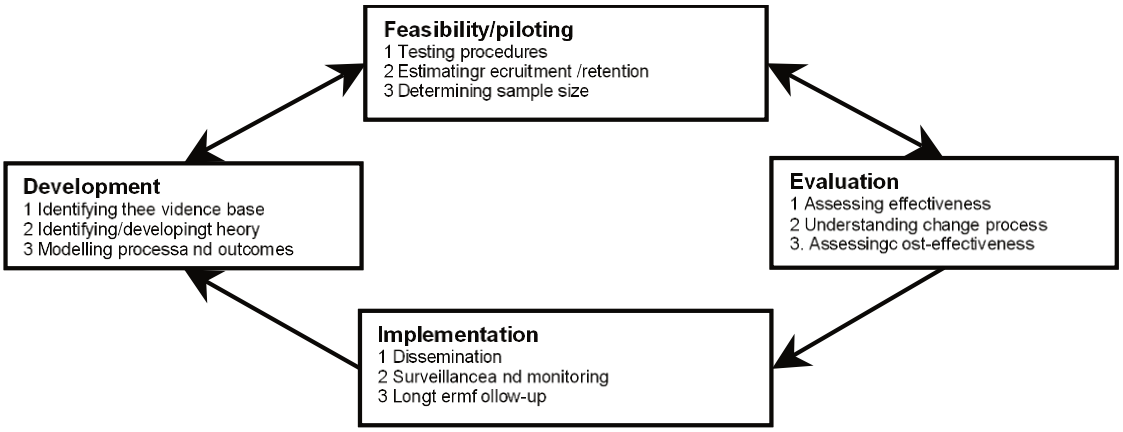
May & Finch (2009) describe it like this:

"… a map of the relations between the core concepts of the theory rather than an empirical map of normalisation processes, and relations between these core concepts are not linear."

Figure 11-3 depicts how in implementation there is no neat progress from A-to-B-to-C. Instead, there is a backwards and forwards motion, a response to contexts, especially at the time of taking action, which sends the activity back round again for further questioning, before normalisation occurs.

There are similarities between Figure 11-3 and earlier diagrams of evaluation methods, such as Figure 11-4, Craig *et al.* (2008), who moved away from a drugs trial format to a more flexible, iterative model, breaking the mould of the time and leaning towards a greater understanding of how and why an intervention worked (see 2.5).

Figure 11-4: Key elements of the development and evaluation process



Taken from Craig *et al.* (2008) – MRC guidance *Developing and evaluating complex interventions: new guidance*. Figure 1.

Step 1 is taken, something is begun, a move is made on to step 2, then a step back might be taken to reinforce step 1. Then a move on to step 3. Again, there is this interplay back and forth between steps.

This desire for a non-linear model reflects a wider concern within implementation science that real-life is often non-linear, but systematic methods tend towards linearity (see 8.6.1). This is seen in Moore *et al.* (2014) where MRC guidance has reverted to a linear model and using it is explained as moving through a step-by-step approach (Moore *et al.*, 2015). Although NPT is not designed to be used as a linear or stepwise framework, rather it recognises the iterative nature of implementation processes, the way it is applied still tends towards a linear approach (see 8.6.1; May & Finch (2009)). This is seen clearly in Sanders, Foster and Ong (2011) who started at Coherence i.e. step 1 and were unable to progress further. May *et al*. (2018) lists many papers that take this linear approach.

In this thesis, using NPT to analyse data from implementing babyClear©, tended towards a linear approach. The analysis followed pre-existing, linear frameworks e.g. babyClear© pathway, logic model, which made it natural to think linearly. Often it seemed one concept needed to be embedded before another could become embedded; not that each generative mechanism (as the concepts were called) had to be complete before another could begin but they did need to be taken in order, for normalisation to occur (see 9.5.1). Only when it made sense (Coherence) and there was buy-in (Cognitive Participation) was there a secure foundation for collective action, and later, review (Reflexive Monitoring). Without Coherence and Cognitive Participation established, it was found to stall at the point of action (see 8.4; 9.4.4). There was evidence of a cyclical element within and between concepts and there were more concepts in play at one time, as the implementation proceeded, nevertheless progress remained primarily linear.

This raises the question of the suitability of NPT when dealing with interventions that tend towards complexity (see 3.4). The benefits of non-experimental methods, like NPT, have been argued in Chapter 2. Orton *et al.* (2017) contend that this includes a non-linear approach, if unpredictable, dynamic, whole-systems, sitting in multidimensional contexts are to be understood. One way to manage this, they suggest, is to employ flexible evaluation methods (Orton *et al.*, 2017). May (2017b) acknowledges that the reader, when considering NPT, must suspend their understanding that contexts are dynamic and non-linear and pretend they are static and linear – clearly this leads to a degree of dissonance and more work is needed to resolve how to fully account for these complex contexts (May *et al.*, 2018). In their latest review (May *et al.*, 2018) the authors posit that the study design tends to direct the way NPT is applied and that NPT is flexible enough to be used meaningfully in multiple conjugations. Nevertheless, a linear view remains the most popular to date.

In summary, NPT acknowledges the dynamic nature of contexts and describes itself as iterative, but in practice is most often applied linearly. This leads to dissonance and tension for the researcher, which has yet to be resolved.

11.6 What NPT adds

Table 11-8: What NPT adds

What NPT added	How?	So what?
Able to identify facilitators	See Chapter 8, especially Tables 8-3 & 8.5	Implementers know what contextual factors to provide, to facilitate the intervention.
Able to identify barriers/threats	See Chapter 8, especially Table 8.5	Implementers know what contextual factors to avoid, to facilitate the intervention.
Able to inform feasibility	See Chapter 8, especially Tables 8-5, 8-7 & 8-8	Implementers know what contextual factors are necessary for the intervention.
Able to inform fidelity	By exploring the programme theory and making mechanisms and active ingredients apparent. See Table 8-7	Clarifying the core ingredients allows practitioners to implement complex interventions with fidelity, while adapting other factors to suit the context.
Able to inform sustainability	See Chapter 8, especially Tables 8-6 & 8-9	Implementers know what ongoing contextual factors are necessary for the intervention.
Able to explore knowledge translation	By exploring the programme theory and making mechanisms and active ingredients apparent and accessible to non-experts. See Table 8-7	Implementers are able to understand what is necessary for the intervention to be normalised and therefore more likely to be able to communicate the requirements for sustainability.
Able to explore theory-practice gap	By exploring the programme theory and making mechanisms and active ingredients apparent and accessible to non-experts. See Tables 8-6, 8-7, 8-9 & 8-10	Offers some of the answers to improving success for sustainability, scaling up and transferring out.